DIN EN ISO/IEEE 11073-10404

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Entwurf

Einsprüche bis 2022-09-01
Vorgesehen als Ersatz für
DIN EN ISO
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Medizinische Informatik – Geräteinteroperabilität – Teil 10404: Kommunikation von Geräten für die persönliche Gesundheit – Gerätespezifikation – Pulsoximeter (ISO/IEEE FDIS 11073-10404:2022); Englische Fassung prEN ISO/IEEE 11073-10404:2022

Health informatics –
Device interoperability –
Part 10404: Personal health device communication – Device specialization – Pulse oximeter
(ISO/IEEE FDIS 11073-10404:2022);
English version prEN ISO/IEEE 11073-10404:2022

Informatique de santé –
Interopérabilité des dispositifs –
Partie 10404: Spécialisation des dispositifs- Oxymètre de pouls
(ISO/IEEE FDIS 11073-10404:2022);
Version anglaise prEN ISO/IEEE 11073-10404:2022

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DIN-Normenausschuss Medizin (NAMed)

Gesamtumfang 89 Seiten

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Nationales Vorwort

Dieses Dokument (prEN ISO/IEEE 11073-10404:2022) 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“ (Sekretariat NEN, Niederlande) erarbeitet.

Für Deutschland hat hieran der Arbeitsausschuss NA 063-07-02 AA „Interoperabilität“ des Fachbereichs 7 „Medizinische Informatik“ im DIN-Normenausschusses Medizin (NAMed) mitgearbeitet.

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

IEEE Std 11073-10101:2019	siehe	DIN EN ISO 11073-10101:2021-01
IEEE Std 11073-20601:2019	siehe	E DIN EN ISO 11073-20601:2022-09

Änderungen

Gegenüber DIN EN ISO 11073-10404:2011-07 wurden folgende Änderungen vorgenommen:

a) IEEE Std 11073-10101:2019 wurde in den Normativen Verweisungen aufgenommen;

b) die Bit-Str in Tabelle 11 und Tabelle 13 wurden in OID-Codes umgewandelt und der ursprüngliche Anhang B wurde gestrichen;

c) in Anhang B wurden MDC_ATTR_MSMT_STAT und MDC_DEV_SPEC_PROFILE_PULS_OXIM aufgenommen und MDC_ATTR_AL_COND entfernt;

d) Ref-ID von MDC_ATTR_AL_OP_STAT und MDC_MOC_SCAN_CFG_PERI und der Codewert von MDC_PULS_OXIM_PULS_CHAR wurden korrigiert;

e) der Qualifier von Transmit-Window wurde in Optional geändert

f) Unterstützung für Base-Offset-Time wurde hinzugefügt;

g) neue Standardkonfigurationen 0x0192 wurde festgelegt;

h) der Abschnitt „Normative Verweisungen“, die Version dieser Gerätespezifikation sowie die darauf basierenden Assoziationsdetails wurden aktualisiert;

i) der Unit-Code und der Unit-LabelString wurden aus den Aufzählungsobjekten entfernt;

j) Aktualisierung des Wortlauts in 6.3 bezüglich „Not Allowed“ und „Observational“;

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k) Hinzufügung einer ICS-Anweisung zur Version der Gerätespezialisierung;

l) Bild 4 wurde korrigiert und ist jetzt konsistent mit dem Beispiel in E.6.2;

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

n) der Text bezüglich „höher als V4“ in 8.3 wurde entfernt;

o) der Qualifier in MDS und anderen Objekten wurde aktualisiert, um Base-Offset-Time zu empfehlen, außerdem wurde die Beschreibung der Qualifier in 6.3 aktualisiert;

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

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

r) der Text in 8.5.2 bezüglich Attribute-Id-List wurde aktualisiert, um mit IEEE Std 11073-20601:2019 konform zu sein;

s) 4.3 „Übereinstimmung mit anderen Normen“ hinzugefügt;

t) Tabelle 1 wurde erweitert, um Qualifier-Details für alle möglichen Konfigurationen anzugeben;

u) Bild 5 und der Zeitstempel in E.6 wurden entfernt;

v) das Bit-Beispiel in E.4.3 wurde aktualisiert, indem die Mds-Time-Info in MDS eingefügt wurde;

w) der Inhalt in Bezug auf „manager-init“ wurde entfernt;

x) Aktualisierung des Wortlauts in 1.3 und 4.1 bezüglich des Vorrangs der Nomenklatur in der Reihe ISO/IEEE 11073 zwischen den Teilen 10101, 20601, 104xx und dieser Norm;

y) die Verwendung der Nomenklaturversion wurde aktualisiert und mit der entsprechenden Protokollversion verknüpft;

z) Jahreszahlen im Literaturverzeichnis wurde entfernt, um immer die neueste Version anzugeben.

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Nationaler Anhang NA
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Nationale Hinweise

NA.1 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 ggf. 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 Pulsoximetern für telemedizinische Anwendungen und Datenverarbeitungsgeräten (wie mobilen Telefonen, Arbeitsplatzrechnern, gesundheitsbezogenen persönlichen Geräten, Settop-Boxen) derart fest, dass "Plug-and-Play"-Interoperabilität ermöglicht wird. Sie benutzt Teile existierende 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 zugrundeliegenden Rahmenbedingungen ein, um Interoperabilität zu erleichtern. Diese Norm legt gemeinsame Kernfunktionen für die Kommunikation persönlicher Pulsoximeter in telemedizinischen Anwendungen 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.

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Nationaler Anhang NB
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Begriffe

Reihenfolge und Inhalt der folgenden Begriffe sind identisch mit denen im Abschnitt Begriffe der englischen Fassung.

3 Begriffe

Für die Anwendung dieses Dokuments gelten die folgenden Begriffe.

ISO und IEC stellen terminologische Datenbanken für die Verwendung in der Normung unter den folgenden Adressen bereit:

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

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

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

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

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

3.4
Gerät
en device
physikalische Apparatur, die entweder eine Agenten- oder eine Managerrolle wahrnimmt

3.5
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

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3.6
Objekt
en object
in der objektorientierten Modellierung, eine besondere Instantiierung einer Klasse. Die Instantiierung legt Attribute, Methoden und Ereignisse der Klasse fest

3.7
persönliches gesundheitsbezogenes Gerät
persönliches telemedizinisches Gerät
en personal health device
personal telehealth device
Gerät, das für persönliche gesundheitsbezogene Anwendungen verwendet wird

3.8
Plethysmogramm
Plethysmografisch
Wellenform des Fotoplethysmografen
en plethysmogram
photoplethysmographic waveform
plethysmographic
Sequenz von Abtastwerten, die der sequentiellen zeitlichen Veränderung der Lichtabsorption durch den Effekt des pulsierenden Blutflusses entspricht

3.9
SpO_2
partielle Sauerstoffsättigung
en SpO_2
prozentuale Sauerstoffsättigung des Hämoglobins, das mit einem Pulsoxymeter gemessen wurde, wobei diese Messung eine Schätzung des Anteils des funktionellen Hämoglobins (oder Hämoglobins) im arteriellen Blut ist, das mit Sauerstoff gesättigt ist

Anmerkung 1 zum Begriff: für weitere Informationen zu SPO_2, siehe ISO 80601-2-61:2017 [B9].

Nationaler Anhang NC
(informativ)

Literaturhinweise

DIN EN ISO 11073-10101:2021-01, *Medizinische Informatik — Geräteinteroperabilität — Teil 10101: Kommunikation patientennaher medizinischer Geräte — Nomenklatur (ISO/IEEE 11073-10101:2020); Englische Fassung EN ISO 11073-10101:2020, nur auf CD-ROM*

E DIN EN ISO 11073-20601:2022-09, *Medizinische Informatik — Geräteinteroperabilität — Teil 20601: Kommunikation von Geräten für die persönliche Gesundheit — Anwendungsprofil — Optimiertes Datenübertragungsprotokoll (ISO/IEEE/FDIS 11073-20601:2022); Englische Fassung prEN ISO 11073-20601:2022*

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This second edition cancels and replaces the first edition (ISO/IEEE 11073-10404:2010), which has been technically revised.

A list of all parts in the ISO/IEEE 11073 series can be found on the ISO website.

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IEEE Std 11073-10404™-2020
(Revision of IEEE Std 11073-10404-2008)

Health informatics—Personal health device communication

Part 10404: Device specialization—Pulse oximeter

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

Approved 30 January 2020
IEEE SA Standards Board

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Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of communication between personal telehealth pulse oximetry devices and compute engines (e.g., cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play interoperability. It leverages appropriate portions of existing standards including ISO/IEEE 11073 terminology, information models, application profile standards, and transport 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 communication functionality for personal telehealth pulse oximeters.

Keywords: IEEE 11073-10404™, medical device communication, personal health devices, PHD, pulse oximeter

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Introduction

This introduction is not part of IEEE Std 11073-10404-2020, Health informatics—Personal health device communication—Part 10404: Device specialization—Pulse oximeter.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. This document uses the optimized framework created in IEEE Std 11073-20601-2019™ and describes a specific, interoperable communication approach for the pulse oximeter.[1] These standards align with, and draw on, the existing clinically focused standards to provide support for communication of data from clinical or personal health devices.

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

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Health informatics—Personal health device communication

Part 10404: Device specialization—Pulse oximeter

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 communication between personal telehealth pulse oximeter devices and compute engines (e.g., cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play (PnP) interoperability. It leverages appropriate portions of existing standards including ISO/IEEE 11073 terminology, information models, application profile standards, and transport 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 communication functionality for personal telehealth pulse oximeters.

1.2 Purpose

This standard addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices (PHDs) and compute engines (e.g., cell phones, personal computers, personal health appliances, 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.

1.3 Context

See IEEE Std 11073-20601-2019™[2] for an overview of the environment within which this standard is written.

This standard, IEEE Std 11073-10404, defines the device specialization for the pulse oximeter, being a specific agent type, and provides a description of the device concepts, its capabilities, and its implementation according to this standard.

This standard is based on IEEE Std 11073-20601-2019, which in turn draws information from both ISO/IEEE 11073-10201:2004 [B6][3] and ISO/IEEE 11073-20101:2004 [B7]. The medical device encoding rules (MDER) used within this standard are fully described in IEEE Std 11073-20601-2019.

[2] Information on references can be found in Clause 2.
[3] The numbers in brackets correspond to the numbers in the bibliography in Annex A.

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This standard defines specialized nomenclature codes that will be collected in IEEE Std 11073-10101-2019™. Between this standard, IEEE Std 11073-10101-2019, IEEE Std 11073-20601-2019 and other IEEE Std 11073-104xx, 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 that is 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 work groups and other stakeholders and any corrective action published as corrigenda.

NOTE—In this standard, ISO/IEEE P11073-104zz is used to refer to the collection of device specialization standards that utilize IEEE Std 11073-20601-2019, where zz can be any number from 01 to 99, inclusive.[4]

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 11073-20601-2019, Health informatics—Personal health device communication—Part 20601: Application profile—Optimized Exchange Protocol.[5, 6]

IEEE Std 11073-10101-2019, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.

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 *IEEE Standards Dictionary Online* [B1] should be referenced for terms not defined in this clause.[7]

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 instantiated from the class utilize.

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

device: A physical apparatus implementing either an agent or manager role.

handle: An unsigned 16-bit number that is locally unique and identifies one of the object instances within an agent.

[4] Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.
[5] IEEE publications are available from The Institute of Electrical and Electronics Engineers (https://standards.ieee.org/).
[6] The IEEE standards or products referred to in Clause 2 are trademarks owned by The Institute of Electrical and Electronics Engineers, Incorporated.
[7] *IEEE Standards Dictionary Online* is available at: http://dictionary.ieee.org. An IEEE Account is required for access to the dictionary, and one can be created at no charge on the dictionary sign-in page.

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manager: A node receiving data from one or more associated agent systems. Examples of managers include a cellular phone, health appliance, set top box, or a computer system.

object: In object-oriented modeling, a particular instantiation of a class. The instantiation realizes attributes, methods, and events from the class.

obj-handle: *See:* **handle**.

personal health device: A device used in personal health applications.

personal telehealth device: *See:* **personal health device**.

photoplethysmographic waveform: *See:* **plethysmogram**.

plethysmogram: Sequence of samples related to the sequential time-varying light absorption due to effects of pulsatile blood flow.

plethysmographic: *See:* **plethysmogram**.

SpO_2: Percentage oxygen saturation of haemoglobin as measured by a pulse oximeter, where this measurement is an estimate of the fraction of functional haemoglobin (or hemoglobin) in arterial blood that is saturated with oxygen.

NOTE—For more information about SpO_2, see ISO 80601-2-61:2017 [B9].

3.2 Acronyms and abbreviations

APDU	application protocol data unit
ASN.1	Abstract Syntax Notation One
DIM	domain information model
EUI-64	extended unique identifier (64 bits)
ICS	implementation conformance statement
ID	identifier
MDC	medical device communication
MDER	medical device encoding rules
MDS	medical device system
MOC	managed object class
OID	object identifier
PDU	protocol data unit
PHD	personal health device
RT-SA	real-time sample array
SpO_2	percentage oxygen saturation of haemoglobin
VMO	virtual medical object

4. Introduction to ISO/IEEE 11073 personal health devices

4.1 General

This standard and the remainder of the series of ISO/IEEE 11073 personal health device (PHD) standards fit in the larger context of the ISO/IEEE 11073 series of standards. The full suite of standards enables agents to interconnect and interoperate with both managers and computerized healthcare information systems. See IEEE Std 11073-20601-2019 for a description of the guiding principles for this series of ISO/IEEE 11073 Personal Health Device standards.

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IEEE Std 11073-20601-2019 supports the modeling and implementation of an extensive set of personal health devices. This standard defines aspects of the pulse oximeter device. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 PHD pulse oximetry agent and a manager. This standard defines a subset of the objects and functionality contained in IEEE Std 11073-20601-2019, extending and adding definitions where appropriate.

All nomenclature codes referenced in this standard are collected in Annex C. Annex C may contain definitions of codes that are used by this standard and that are not yet present in the referenced versions of IEEE Std 11073-10101-2019 and IEEE Std 11073-20601-2019.

4.2 Introduction to IEEE 11073-20601 modeling constructs

4.2.1 General

The ISO/IEEE 11073 series of standards, and in particular IEEE Std 11073-20601-2019, is based on an object-oriented systems management paradigm. The overall system model is divided into three principal components: the domain information model (DIM), the service model, and the communication model. See IEEE Std 11073-20601-2019 for a detailed description of the modeling constructs.

4.2.2 Domain information model (DIM)

The DIM is a hierarchical model that describes an agent as a set of objects. These objects and their attributes represent the elements that control behavior and report on the status of the agent and data that an agent can communicate to a manager. Communication between the agent and manager is defined by the application protocol in IEEE Std 11073-20601-2019.

4.2.3 Service model

The service model defines the conceptual mechanisms for the data exchange services. Such services are mapped to messages that are exchanged between the agent and manager. Protocol messages within the ISO/IEEE 11073 series of standards are defined in ASN.1. The messages defined in IEEE Std 11073-20601-2019 can coexist with messages defined in other standard application profiles defined in the ISO/IEEE 11073 series of standards.

4.2.4 Communication model

In general, the communication model supports the topology of one or more agents communicating over logical point-to-point connections to a single manager. For each logical point-to-point connection, the dynamic system behavior is defined by a connection state machine as specified in IEEE Std 11073-20601-2019.

4.2.5 Implementing the models

An agent implementing this standard shall implement all mandatory elements of the information, service, and communication models as well as all conditional elements where the condition is met. The agent should implement the recommended elements, and it may implement any combination of the optional elements. A manager implementing this standard shall utilize at least one of the mandatory, conditional, recommended, or optional elements. In this context, “utilize” means to use the element as part of the primary function of the manager device. For example, a manager whose primary function is to display data would need to display a piece of data in the element in order to utilize it.

4.3 Compliance with other standards

Devices that comply with this standard may also be required to comply with other domain- and device-specific standards that supersede the requirements of this standard with respect to issues including safety,

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reliability, and risk management. A user of this standard is expected to be familiar with all other such standards that apply and to comply with any higher specifications thus imposed.

Typically, medical devices should comply with the IEC 60601-1 [B2] base standards with respect to electrical and mechanical safety and any device-specific standard as might be defined in the IEC 60601-2 [B3] series of standards. Software aspects may apply through standards such as IEC 62304/EN 62304 [B4]. Devices that comply with this standard implement higher layers of network software and utilize lower layers as appropriate to the application. The requirements on performance of such applications and conformance are defined elsewhere and are outside the scope of this standard. Moreover, the use of any medical equipment is subject to risk assessment and risk management appropriate to the application. Some relevant examples are ISO 14971:2007 [B8] and IEC 80001-1 [B5]. The requirements of such risk assessment, risk management, and conformance are outside the scope of this standard. The applicable versions of the referenced safety related standards may differ per country.

5. Pulse oximeter device concepts and modalities

5.1 General

This clause presents the general concepts of pulse oximeter equipment. In the context of PHDs in the ISO/IEEE 11073 family of standards, a pulse oximeter, also called an oximeter, provides a noninvasive estimate of functional oxygen of arterial haemoglobin (SpO_2) from a light signal interacting with tissue, by using the time-dependent changes in tissue optical properties that occur with pulsatile blood flow (see Draft Guidance for Industry and FDA Staff **Error! Reference source not found.**). Applying the Beer-Lambert law of light absorption through such an arterial network, the fraction of oxygenation of arterial haemoglobin can be estimated. This estimate, normally expressed as a percentage by multiplying that fraction by 100, is known as SpO_2. Occasionally, this estimate may be referenced as $\%SpO_2$. ISO 80601-2-61:2017 [B9] contains additional information applicable to pulse oximetry.

5.2 Device types

Pulse oximeter systems with applicability in the personal health space may take on a variety of configurations and sensor compositions, and their configurations have suitability in different personal health application spaces. Pulse oximeter equipment comprises a pulse oximeter monitor, a pulse oximeter probe, and a probe cable extender, if provided. Some oximeters are all-in-one assemblies, where the optical probe, processing, and display components are in a single package. Other oximeters may consist of separate sensor and processing/display components. Still others may place the sensor and signal processing in one component, and send that information into an external component for display and storage. Pulse oximeters may place sensors in numerous locations on the body and use transconductance and reflectance of the light path. This standard assumes all measurements are equal and provides a single measure with no differentiation of location. In addition, other configurations may add storage capability into the system. This implies that different information models may be best suited for each particular device configuration.

5.3 General concepts

5.3.1 Noninvasive measurement

The scope of this specialization covers the intended use of pulse oximeter equipment, which includes, but is not limited to, the estimation of arterial oxygen haemoglobin saturation and pulse rate. This standard is not applicable to pulse oximeter equipment intended for use in laboratory research applications or to oximeters that require a blood sample (see ISO 80601-2-61:2017 [B9]). This standard does not cover measurement of oxygenation via blood extraction. This standard is not applicable to pulse oximeter equipment solely intended for foetal use.

The sensing mechanism may use either transmissive or reflective methods to measure blood oxygenation.

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In addition, blood oxygenation is usually determined as a ratio of the absorbance of two different wavelengths of light, although more wavelengths may be used.

5.3.2 Acquisition modes

5.3.2.1 General

Pulse oximeters are used to measure SpO_2 within a variety of use scenarios.

5.3.2.2 Spot-check

In a spot-check scenario, a user may simply want to take a single, fully processed reading for transmission to a manager. For example, the user would attach the oximeter, whereupon the agent would take an oximetry and pulse rate reading. The agent would then begin communication with a manager and send that single reading. The manager may acknowledge the transmission so the agent can subsequently disassociate and return to its prior state.

5.3.2.3 Continuous monitoring

A continuous monitoring situation involves the pulse oximeter device measuring the user's oxygenation for some period of time greater than that needed to acquire a single measurement. Multiple measurements may be taken to acquire trending information.

5.3.2.4 Stored-and-forwarded measurements

Stored-and-forwarded measurements could be considered as a specialized, continuous monitoring application where the pulse oximetry device is not always in communication with a manager, and the oximeter records data over several minutes or hours. In this case, oximetry data are stored in the device for the duration of the study session and subsequently transferred to the manager at an appropriate time. This measurement communication style is distinct from the situation where temporarily stored measurements are transferred when the communication link is restored.

5.4 Collected data

5.4.1 General

This subclause describes the nature of the data that have been collected based on the acquisition modes described in 5.3.2.

5.4.2 Percentage of arterial haemoglobin oxygen saturation

5.4.2.1 SpO_2

Every oximeter sends at least one expression of SpO_2. This is the primary measurement of a pulse oximeter. It is important to note that this measurement is determined through various signal processing techniques and can be expressed in different ways. Each method and expression has its applicability in particular application spaces (e.g., vital signs monitoring and diagnostic sleep studies). Often the reported SpO_2 has been processed with a variety of techniques in order to present the data for use in a number of ways.

In response to the various physiological phenomena and situations, SpO_2 measurements may be expressed in a variety of ways. Additional modalities for expressing SpO_2 are often used that are better suited to expose or suppress various physiological or environmental phenomena, as seen in 5.4.2.2. The following subclause outlines three expressions of SpO_2 that may be used by a device manufacturer to convey blood oxygenation level.

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It is also conceivable that pulse oximeter equipment may deliver a single SpO_2 that is determined by one of these modalities. Furthermore, several of these distinct expressions may be transmitted concurrently during a measurement session. The manager, upon receiving this collection of information, may choose to display another subset of these expressions. It is required for a pulse oximeter agent to support at least one instance of this measurement.

5.4.2.2 Alternative expressions of SpO_2

One case of SpO_2 measurement involves a user wearing a sensor during unintentional or moderate activity. The result of this activity may be intermittent loss of signal acquisition. The most common expression of SpO_2 may be too sensitive to these effects and could result in a fluctuating (and, therefore, misleading) reading. An SpO_2 measurement modality known as "slow-response" modality has a characteristic that "smooths out" a series of measurements in some fashion, perhaps by changing an averaging parameter or by employing a different algorithm. This modality is defined in this standard.

During a sleep study, an apnea event results in a rapid desaturation of blood oxygenation. This SpO_2 measurement can be expressed by a "fast-response" modality that uses a technique that more effectively captures such events. The technique may vary among device manufacturers, but a distinct expression able to capture these rapid changes is defined in this standard.

The terms *slow-response* and *fast-response* are relative to a particular implementation and are not intended to show a comparison across devices or vendors. Note that these are descriptive terms intentionally left unspecific to allow more flexible interpretations within a particular implementation.

A pulse oximeter will often send SpO_2 measurements periodically; e.g., once every second. In addition, pulse oximeters may begin outputting measurements as soon as it has a reasonable estimate of functional haemoglobin oxygenation. Subsequent measurements may, in some fashion, converge on the oximeter's best estimate. An additional modality, the "spot-check" modality, fulfills the desire to be able to perform and display a single SpO_2 measurement that is also its best estimate of functional haemoglobin oxygenation. In other words, a spot-check is not simply the first measurement, but the first *best* measurement. The specific manner in which this measurement is produced is specific to the pulse oximeter implementation. Once that measurement is transmitted, the measurement session is complete.

5.4.3 Pulse rate

The heart rate measured by a pulse oximeter is produced by a heartbeat, but also requires ejection of blood by the heart and generation of an arterial and tissue pressure wave that is detectable by photoplethysmographic means. Therefore, the pulse rate may be a less reliable measure of heart rate than that of directly measuring by electrocardiograph (ECG). As described in 5.4.2.1 and 5.4.2.2, the reported value or values may be determined in a variety of ways, and corresponding modalities of "slow-response," "fast-response," and "spot-check" are defined for pulse rate measurements. It is required for a pulse oximeter agent to support at least one instance of this feature.

5.4.4 Pulsatile occurrence

If a precisely timestamped occurrence of a pulse is transmitted to a manager, that information can be used in conjunction with other reported physiological events to derive another physiological measurement. Other application spaces may wish to indicate pulsatile occurrence with less precision for purposes of displaying, for instance, a flashing heart icon. It is not required for a pulse oximeter agent to support this feature.

5.4.5 Plethysmogram

There are applications where it is desired to visualize the sequence of samples related to the time-varying light absorption due to the effects of pulsatile blood flow. Often these samples are taken from a single wavelength light source, usually the wavelength less affected by changes in oxygen saturation. It is not required for a pulse oximeter agent to support this feature.

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5.4.6 Pulsatile quality and signal characterization

Pulse oximeter manufacturers have many ways to characterize the quality of the pulsatile wave. Unfortunately, no industry-wide standard currently exists to quantify the characteristics of the signal. However, signal amplitude metrics among the different vendors provide quantities that can be found to have a linear relationship. One notable characteristic is the amplitude of the signal modulation. Other methods to characterize the quality of the pulsatile wave may be employed. It is not required for a pulse oximeter to support this feature.

5.5 Derived data

5.5.1 Limit indications

Pulse oximeters may implement indicators based on monitoring physiological values as falling outside predefined limits. The commonly implemented indicators include reaching the thresholds of a high or low SpO_2, or reaching the thresholds of a high or low pulse rate.

5.5.2 Pulsatile status

Pulse oximeters may provide status indications of certain characteristics of a pulsatile wave or irregularities in the waveform.

5.5.3 Device and sensor status

Pulse oximeters may provide status indications pertaining to sensor malfunction or dislodgement as well as various signal anomalies.

5.6 Stored data

As stated in 5.3.2.4, a pulse oximeter may be used over one or more sessions of several hours without being in contact with a manager to send its data. After the session or sessions are completed, the pulse oximeter agent connects to a manager. The manager is able to select which of the agent's stored sessions to retrieve. The agent then transmits the manager's selection in one or several blocks of messages for processing by a manager or other processing apparatus. The manager is also able to choose a set of sessions for deletion.

5.7 Device configurations

Although agents typically have a static configuration, it is permissible and desirable for an agent to support multiple configurations, one of which would be active at any given time. Pulse oximeters may have a rich set of features that can be combined into a collection of different configurations, one of which can be selected by the manager during configuration.

Two general categories of configurations exist. The first category is known as the set of standard configurations. These are intended to describe a relatively limited feature set of a single device specialization, which have predefined configuration identity (ID) codes. Managers may be pre-loaded with these configurations, in which case the configuration process is eliminated and immediate operation is allowed. The second category involves the set of extended configurations. These configurations are more flexible in that they may include concepts particular to one or more device specializations or include other features as defined in this standard.

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