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Health informatics — Personal health device communication —

Part 10404: Device specialization — Pulse oximeter

Informatique de santé — Communication entre dispositifs de santé personnels —

Partie 10404: Spécialisation des dispositifs — Oxymètre de pouls

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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ISO/IEEE 11073-10404 was prepared by the 11073 Committee of the Engineering in Medicine and Biology Society of the IEEE (as IEEE Std 11073-10404-2008). It was adopted by Technical Committee ISO/TC 215, *Health informatics*, in parallel with its approval by the ISO member bodies, under the “fast-track procedure” defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE. Both parties are responsible for the maintenance of this document.

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 10101: (Point-of-care medical device communication) Nomenclature*

— *Part 10201: Domain information model*

— *Part 10404: Device specialization — Pulse oximeter*

— *Part 10407: Device specialization — Blood pressure monitor*

— *Part 10408: (Point-of-care medical device communication) Device specialization — Thermometer*

— *Part 10415: (Point-of-care medical device communication) Device specialization — Weighing scale*

— *Part 10417: Device specialization — Glucose meter*

— *Part 10471: (Point-of-care medical device communication) Device specialization — Independant living activity hub*

— *Part 20101: (Point-of-care medical device communication) Application profiles — Base standard*

— *Part 20601: (Point-of-care medical device communication) 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*

Introduction

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. This standard uses the optimized framework created in IEEE Std 11073-20601™-2008[a] and describes a specific, interoperable communication approach for pulse oximeters. These standards align with, and draw upon, the existing clinically focused standards to provide support for communication of data from clinical or personal health devices.

[a] For information on references, see Clause 2.

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 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 11073-20601-2008[1] for an overview of the environment within which this standard is written.

This standard, IEEE Std 11073-10404-2008, 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 11073-20601-2008, which in turn draws information from both ISO/IEEE 11073-10201:2004 [B3][2] and ISO/IEEE 11073-20101:2004 [B4]. The medical device encoding rules (MDER) used within this standard are fully described in IEEE Std 11073-20601-2008.

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 11073-20601-2008, all required nomenclature codes for implementation are documented.

NOTE—In this standard, ISO/IEEE P11073-104zz is used to refer to the collection of device specialization standards that utilize IEEE Std 11073-20601-2008, where zz can be any number from 01 to 99, inclusive.[3]

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.[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* [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, methods, and events that objects instantiated from the class utilize.

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

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

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

[1] Information on references can be found in Clause 2.
[2] The numbers in brackets correspond to the numbers in the bibliography in Annex A.
[3] Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.
[4] IEEE publications are available from the Institute of Electrical and Electronics Engineers, 445 Hoes Lane, Piscataway, NJ 08854, USA (http://standards.ieee.org/).

3.1.6 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.

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

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

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

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

3.1.11 plethysmogram, plethysmographic, or **photoplethysmographic waveform:** Sequence of samples related to the sequential time-varying light absorption due to effects of pulsatile blood flow.

3.1.12 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 9919 [B6].

3.2 Acronyms and abbreviations

APDU	application protocol data unit
ASN.1	Abstract Syntax Notation One
DIM	domain information model
ECG	electrocardiograph
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
PnP	plug-and-play
RT-SA	real-time sample array
SpO_2	percentage oxygen saturation of haemoglobin
VMO	virtual medical object
VMS	virtual medical system

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 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 managers and with computerized healthcare information systems. See IEEE Std 11073-20601-2008 for a description of the guiding principles for this series of ISO/IEEE 11073 personal health device standards.

IEEE Std 11073-20601-2008 supports the modeling and implementation of an extensive set of personal health devices. IEEE Std 11073-10404-2008 (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 personal health device pulse oximetry agent and a manager. This standard

defines a subset of the objects and functionality contained in IEEE Std 11073-20601-2008, extending and adding definitions where appropriate. All new definitions are given in Annex B in Abstract Syntax Notation One (ASN.1). Nomenclature codes referenced in this standard, which are not defined in IEEE Std 11073-20601-2008, are normatively defined in Annex C.

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 11073-20601-2008, 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 11073-20601-2008 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 11073-20601-2008.

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 11073-20601-2008 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 11073-20601-2008.

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.

5. Pulse oximeter device concepts and modalities

5.1 General

This clause presents the general concepts of pulse oximeter equipment. In the context of personal health devices 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 [B5]). 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 9919 [B6] 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. 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 9919 [B6]). 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. 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.

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 “smoothes 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.

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.