INTERNATIONAL STANDARD

ISO/IEEE 11073-10421

First edition
2012-11-01

Health informatics — Personal health device communication —

Part 10421: Device specialization — Peak expiratory flow monitor (peak flow)

Informatique de santé — Communication entre dispositifs de santé personnels —
Partie 10421: Spécialisation de dispositif — Moniteur du flux rexpiratoire de crête (flux de crête)

Reference number
ISO/IEEE 11073-10421:2012(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Institute of Electrical and Electronics Engineers, Inc.
3 Park Avenue, New York • NY 10016-5997, USA
E-mail stds.ipr@ieee.org
Web www.ieee.org

Published in Switzerland

Contents

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.

IEEE Standards documents are developed within the IEEE Societies and the Standards Coordinating Committees of the IEEE Standards Association (IEEE-SA) Standards Board. The IEEE develops its standards through a consensus development process, approved by the American National Standards Institute, which brings together volunteers representing varied viewpoints and interests to achieve the final product. Volunteers are not necessarily members of the Institute and serve without compensation. While the IEEE administers the process and establishes rules to promote fairness in the consensus development process, the IEEE does not independently evaluate, test, or verify the accuracy of any of the information contained in its standards.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is called to the possibility that implementation of this standard may require the use of subject matter covered by patent rights. By publication of this standard, no position is taken with respect to the existence or validity of any patent rights in connection therewith. ISO/IEEE is not responsible for identifying essential patents or patent claims for which a license may be required, for conducting inquiries into the legal validity or scope of patents or patent claims or determining whether any licensing terms or conditions provided in connection with submission of a Letter of Assurance or a Patent Statement and Licensing Declaration Form, if any, or in any licensing agreements are reasonable or non-discriminatory. Users of this standard are expressly advised that determination of the validity of any patent rights, and the risk of infringement of such rights, is entirely their own responsibility. Further information may be obtained from ISO or the IEEE Standards Association.

ISO/IEEE 11073-10421 was prepared by the IEEE 11073 Standards Comittee of the IEEE Engineering in Medicine and Biology Society (as IEEE Std 11073-10421-2010). 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. IEEE is responsible for the maintenance of this document with participation and input from ISO member bodies.

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: (Point-of-care medical device communication) Domain information model*

— *Part 10404: Device specialization — Pulse oximeter*

— *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 10420: Device specialization — Body composition analyzer*

— *Part 10421: Device specialization — Peak expiratory flow monitor (peak flow)*

— *Part 10471: Device specialization — Independant 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*

Introduction

This introduction is not part of IEEE Std 11073-10421-2010, Health informatics—Personal health device communication—Part 10421: Device specialization—Peak expiratory flow monitor (peak flow).

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. This document uses the optimized framework created in IEEE Std 11073-20601-2008[a] and describes a specific, interoperable communication approach for weighing scales. 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 10421: Device specialization — Peak expiratory flow monitor (peak flow)

1 Overview

1.1 Scope

The scope of this standard is to establish a normative definition of communication between personal telehealth peak flow monitoring devices (agents) and managers (e.g., cell phones, personal computers, personal health appliances, and set top boxes) in a manner that enables plug-and-play interoperability. It leverages work done in other ISO/IEEE 11073 standards including existing terminology, information profiles, application profile standards, 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 functionality of a peak-flow monitoring device. The use case is restricted to personal respiratory monitoring and therefore does not include hospital-based spirometry. Continuous and high-acuity monitoring (e.g., for emergency response) are outside the scope of the use case.

In the context of personal health devices, a peak flow meter is a device used to measure the respiratory function of those managing respiratory conditions such as asthma and chronic obstructive pulmonary disease. The ability to identify declining respiratory status prior to the need for acute intervention improves the quality of life for the individual while reducing the overall costs of care. Respiratory status data are collected by a personal respiratory monitoring device and forwarded to a central data repository for review and action by a health care provider. The data are episodic in nature and are forwarded at designated intervals or when the person is symptomatic.

This standard provides the data modeling and its transport shim layer according to IEEE Std 11073-20601™-2008 and does not specify the measurement method.

1.2 Purpose

This standard addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices (agents) and managers (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 for an overview of the environment within which this standard is written.

This standard defines the device specialization for the peak expiratory flow monitor, 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 11073-20601-2008, which in turn draws information from both ISO/IEEE Std 11073-10201:2004 [B2][1] and ISO/IEEE Std 11073-20101:2004 [B3]. The medical device encoding rules (MDERs) 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 [B1] 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.[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—Application profile—Optimized Exchange Protocol.[3,4]

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

NOTE—IEEE Std 11073-20601-2008 is referenced throughout this standard as IEEE Std 11073-20601.

[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.
[3]The IEEE standards or products referred to in this clause are trademarks of the Institute of Electrical and Electronics Engineers, Inc.
[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 Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this document, the following terms and definitions apply. *The IEEE Standards Dictionary: Glossary of Terms & Definitions* should be referenced for terms not defined in this clause.[5]

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 term used to refer to a physical apparatus implementing either an agent or a manager role.

3.1.5 forced expiratory volume: The expiratory volume of a subject under forced conditions at time t in seconds, measured from time zero.

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

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

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

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

3.1.10 peak expiratory flow: maximum flow measured at the mouth during an expiration delivered with maximal force starting immediately after achieving maximum lung inflation.

3.1.11 peak expiratory flow monitor: A medical device used to measure the respiratory function of those managing respiratory conditions such as asthma.

3.1.12 personal best: This value is determined by a healthcare professional or based on predicted average peak flow and is typically the highest peak expiratory flow (PEF) reading an individual can obtain while in peak condition.

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

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

3.1.15 predicted average peak flow: The value of peak expiratory flow that is calculated based on the user's age, height, and sex to serve as a benchmark for the user's measurements.

3.1.16 time zero: In the context of this document, time zero is the instant at which a user starts blowing into the peak-flow monitor to record a measurement.

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)
FEV	forced expiratory volume

[5] *The IEEE Standards Dictionary: Glossary of Terms & Definitions* is available at http://shop.ieee.org/.

FEV1	forced expiratory volume in 1 s
FEV6	forced expiratory volume in 6 s
ICS	implementation conformance statements
MDC	medical device communication
MDER	medical device encoding rules
MDS	medical device system
MOC	managed object class
OID	object identified
PDU	protocol data unit
PEF	peak expiratory flow
PHD	personal health device
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 (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 managers and with computerized health-care information systems. See IEEE Std 11073-20601 for a description of the guiding principles for this series of ISO/IEEE 11073 Personal Health Device standards.

IEEE Std 11073-20601 supports the modeling and implementation of an extensive set of personal health devices. This standard defines aspects of the peak expiratory flow monitor device. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 PHD peak expiratory flow monitor agent and a manager. This standard defines a subset of the objects and functionality contained in IEEE Std 11073-20601 and extends and adds definitions where appropriate. All new definitions are given in Annex B in Abstract Syntax Notation One (ASN.1) [B4]. Nomenclature codes referenced in this standard, which are not defined in IEEE Std 11073-20601, 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, 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 for a detailed description of the modeling constructs.

4.2.2 Domain information model

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 the manager is defined by the application protocol in IEEE Std 11073-20601.

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 the manager. Protocol messages within the ISO/IEEE 11073 series of standards are defined in ASN.1. The messages defined in IEEE Std 11073-20601

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. The security of this communication is largely determined by, but not limited to, the physical security of the device along with the inherent security of the underlying transports. Additional security may be defined by future revisions of IEEE Std 11073-20601.

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 Peak expiratory flow monitor device concepts and modalities

5.1 General

This clause presents the general concepts of peak expiratory flow monitor devices. In the context of personal health devices in this family of standards, a peak expiratory flow monitor is a device that measures the respiratory function of those managing respiratory conditions such as asthma. In general, the peak expiratory flow monitor will be taking measurements of the lung function of the subject by recording the flow and volume of air during exhalation with maximum effort. Typically, a peak expiratory flow monitor accomplishes this task by measuring and recording peak expiratory flow (PEF) and forced expiratory volume in 1 s (FEV1). In some cases, forced expiratory volume in 6 s (FEV6) is also measured.

The methods to determine PEF and forced expiratory volume (FEV) vary, but common methods include the use of pressure sensors, mechanical turbines, piezo-electric crystals, and so on as sensors. The subject is required to deliver an expiration with maximal force into a mouthpiece that channels the air to the sensor. Typically, the sensor will measure airflow to determine PEF, and from the area of the tube in which the sensor is placed, the volume (FEV1 or FEV6) may be calculated.

5.2 PEF

PEF is a measure of how fast an individual can push air out of their lungs after taking a maximal inspiration and followed by a maximal expiration. PEF is measured in liters per minute. Figure 1 shows the typical rate of flow during the measurement of PEF with the maximal value at around 0.1 s.

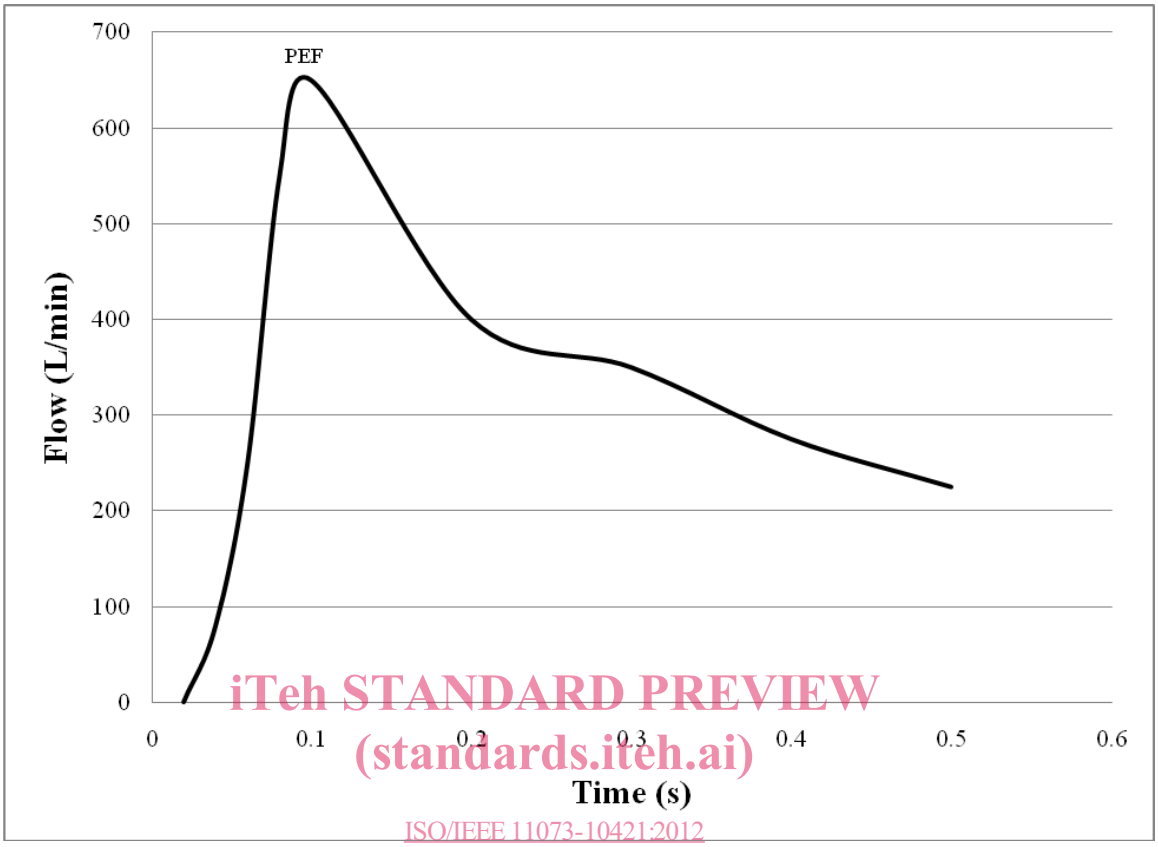

Figure 1—PEF waveform (representation only—does not correspond to real values)

5.3 Personal best

Personal best is not a constantly measured value; rather, it is determined by a health-care professional or based on predicted average peak flow. The personal best is typically the highest PEF reading an individual can obtain while in peak condition. Personal best, as a value of PEF, is measured in liters per minute.

5.4 FEV1

FEV1 is a measure of forced expiratory volume. It is a measure of expiratory volume of a subject under forced conditions at 1 s, measured from time zero (time at which subject starts the expiration). FEV1 is measured in liters. Figure 2 shows a typical pulmonary waveform where FEV1 is the total volume of air and would be calculated as the area under the curve between 0 s and 1 s.

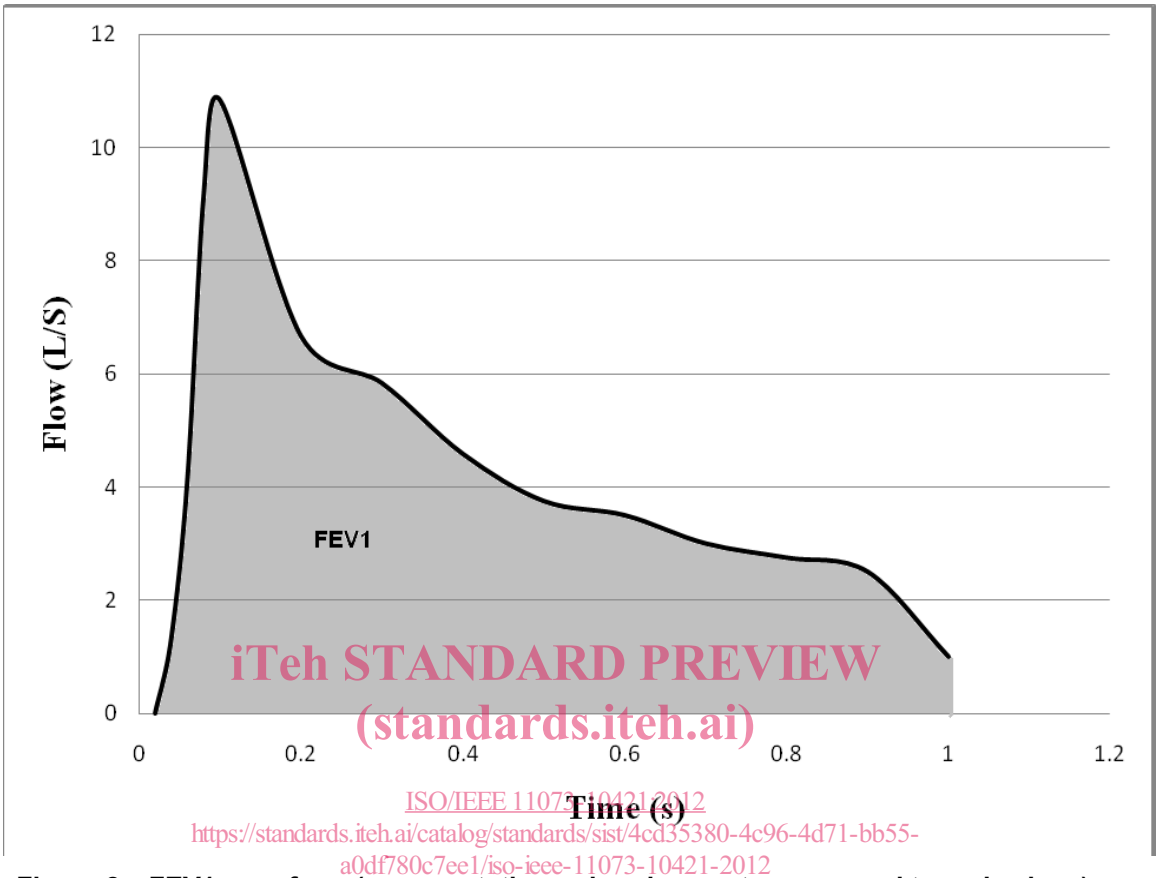

Figure 2—FEV1 waveform (representation only—does not correspond to real values)

5.5 FEV6

FEV6 is a measure of the forced expiratory volume of a subject under forced conditions at 6 s measured from time zero. FEV6 is measured in liters.

6 Peak expiratory flow monitor domain information model

6.1 Overview

This subclause describes the domain information model of the peak expiratory flow monitor.

6.2 Class extensions

In this standard, no class extensions are defined with respect to IEEE Std 11073-20601.

6.3 Object instance diagram

The object instance diagram of the peak expiratory flow monitor domain information model, defined for the purposes of this standard, is shown in Figure 3.