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**Medizinische Informatik –
Kommunikation von Geräten für die persönliche Gesundheit –
Teil 10421: Gerätespezifikation – Monitor für den maximalen
expiratorischen Atemfluss (peak flow) (ISO 11073-10421:2012);
Englische Fassung EN ISO 11073-10421:2012**

Health informatics –

Personal health device communication –

Part 10421: Device specialization – Peak expiratory flow monitor (peak flow)
(ISO 11073-10421:2012);

English version EN ISO 11073-10421:2012

Informatique de santé –

Communication entre dispositifs de santé personnels –

Partie 10421: Spécialisation des dispositifs – Moniteur de surveillance du débit expiratoire
de pointe (débit de pointe) (ISO 11073-10421:2012);

Version anglaise EN ISO 11073-10421:2012

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Normenausschuss Medizin (NAMed) im DIN

Nationales Vorwort

Diese Norm enthält unter Berücksichtigung des Präsidialbeschlusses 13/1983 den englischen Originaltext der internationalen Norm EN ISO/IEEE 11073-10421:2012. Die Internationale Norm wurde in der WG 7 „Devices“ des ISO/TC 215 „Health informatics“ in Zusammenarbeit mit dem IEEE „Institute of Electrical and Electronics Engineers“ erarbeitet und wird parallel im CEN/TC 251 „Medizinische Informatik“ abgestimmt. Der Arbeitsausschuss NA 063-07-02 AA „Interoperabilität“ des Fachbereichs 7 „Medizinische Informatik“ des Normenausschusses Medizin im DIN hat an der Erarbeitung mitgewirkt.

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

IEEE Std 11073-20601:2008 siehe DIN EN ISO 11073-20601:2011-07

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 Monitoren für den maximalen expiratorischen Atemfluss 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 zugrunde liegenden Rahmenbedingungen ein, um Interoperabilität zu erleichtern. Diese Norm legt gemeinsame Kernfunktionen für die Kommunikation persönlicher Monitore für den maximalen expiratorischen Atemfluss in telemedizinischen Anwendungen fest. Der Use Case wird auf persönliche Überwachung der Atmung eingeschränkt und bezieht sich nicht auf die Spirometrie im Krankenhaus. Die dauerhafte und hochscharfe Überwachung (z. B. für Notfallmaßnahmen) liegen außerhalb des Geltungsbereichs des Use Cases. Im Zusammenhang mit den Geräten für die persönliche Gesundheit, ist ein Monitor für den maximalen expiratorischen Atemfluss ein Gerät, das verwendet wird, um die Atemfunktion bei Atemwegserkrankungen wie Asthma und COPD zu messen. Die Fähigkeit einen rückläufigen respiratorischen Status zu erkennen, bevor eine Notwendigkeit für eine akute Intervention besteht, verbessert die Qualität des Lebens für den Einzelnen bei gleichzeitiger Reduzierung der Gesamtkosten für die Pflege. Der Status von Atmungsdaten wird durch eine persönliche Überwachung der Atmung im Gerät gesammelt und an ein zentrales Daten-Repository für die Überprüfung

und Handlung an einen Leistungserbringer übermittelt. Die Daten sind episodischer Natur und werden in festgelegten Intervallen weitergeleitet oder wenn sich für die Person gefährliche Symptome zeigen. Diese Norm regelt die Datenmodellierung und den Datentransport in einer Shim-Schicht nach der Norm ISO/IEEE11073-20601, und legt nicht das Messverfahren fest.

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

Begriffe

Begriff in Englisch	Begriff in Deutsch
agent A node that collects and transmits personal health data to an associated manager.	Agent Ein Knoten, der persönliche Gesundheitsdaten sammelt und an einen angeschlossenen Manager weiterleitet.
class In object-orientated modeling, a class describes the attributes, methods, and events that objects instantiated from the class utilize.	Klasse Im objektorientierten Modell beschreibt eine Klasse die Attribute, Methoden und Ereignisse, die Objekte benutzen, welche aus dieser Klasse instantiiert werden.
compute engine; 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.	(Verarbeitungsmaschine); Manager Ein Knoten, der Daten von einem oder mehreren Agentensystem erhält. Manager können z. B. auch mobile Telefone, gesundheitsbezogene Geräte, Digitalempfänger oder Computersysteme sein.
device A term used to refer to a physical apparatus implementing either an agent or manager role.	Gerät Ein Begriff, der sich auf eine physikalische Apparatur, die entweder eine Agenten- oder eine Managerrolle wahrnimmt, bezieht.
forced expiratory volume The expiratory volume of a subject under forced conditions at time t in seconds, measured from time zero.	erzwungenes expiratorisches Volumen Das expiratorische Volumen eines Subjekts unter erzwungenen Bedingungen zum Zeitpunkt t in Sekunden vom Zeitpunkt Null an gemessen.
handle, obj-handle An unsigned 16-bit number that is locally unique and identifies one of the objects instance within an agent.	Dateinummer (en: handle); Objekt-handle Eine vorzeichenlose 16-bit-Zahl, die lokal einmalig vergeben wird und der Identifizierung der Objektinstanz in einem Agenten dient.
object In object-orientated modeling, a particular instantiation of a class. The instantiation realizes attributes, methods, and events from the class.	Objekt In der objektorientierten Modellierung, eine besondere Instantiierung einer Klasse. Die Instantiierung legt Attribute, Methoden und Ereignisse der Klasse fest.
peak expiratory flow Maximum flow measured at the mouth during an expiration delivered with maximal force starting immediately after achieving maximum lung inflation.	maximaler expiratorischer Atemfluss Maximaler Durchfluss gemessen im Mund, der beim Ausatmen mit maximaler Kraft sofort nach Erreichen des maximalen Füllvolumens der Lunge erreicht werden kann.

Begriff in Englisch	Begriff in Deutsch
peak expiratory flow monitor A medical device used to measure the respiratory function of those managing respiratory conditions such as asthma.	Monitor für den maximalen expiratorischen Atemfluss Ein Medizingerät, das benutzt wird, um die Atemfunktion bei Atemwegserkrankungen wie Asthma zu messen.
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.	persönlicher Bestwert Dieser Wert wird von medizinischem Fachpersonal bestimmt oder basiert auf einem prognostizierten durchschnittlichen maximalen Atemfluss, dies ist in der Regel der höchste maximale expiratorische Atemfluss (en: peak expiratory flow, PEF), während der Aufnahme, den ein Einzelner erreichen kann, wenn er in Topform ist.
personal health device; personal telehealth device A device used in personal health applications.	persönliches gesundheitsbezogenes Gerät; persönliches telemedizinisches Gerät Ein Gerät, das für persönliche gesundheitsbezogene Anwendungen verwendet wird.
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.	prognostizierte durchschnittliche maximaler Atemfluss Der Wert des maximalen expiratorischen Atemflusses, der auf Grundlage von Alter, Größe und Geschlecht des Benutzers berechnet wird und als Maßstab für die Messungen des Benutzers dient.
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.	Zeit Null Im Kontext dieses Dokuments ist die Zeit Null der Zeitpunkt, zu dem ein Benutzer beginnt in den Maximalen-Atemfluss-Monitor zu blasen, um eine Messung aufzunehmen.

Nationaler Anhang NA (informativ)

Literaturhinweise

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

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English Version

Health informatics - Personal health device communication -
Part 10421: Device specialization - Peak expiratory flow monitor
(peak flow) (ISO 11073-10421:2012)

Informatique de santé - Communication entre dispositifs de
santé personnels - Partie 10421: Spécialisation des
dispositifs - Moniteur de surveillance du débit expiratoire de
pointe (débit de pointe) (ISO 11073-10421:2012)

Medizinische Informatik - Kommunikation von Geräten
für die persönliche Gesundheit - Teil 10421:
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Foreword

This document (EN ISO 11073-10421:2012) 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.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by May 2013, and conflicting national standards shall be withdrawn at the latest by May 2013.

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Endorsement notice

The text of ISO 11073-10421:2012 has been approved by CEN as a EN ISO 11073-10421:2012 without any modification.

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.

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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.

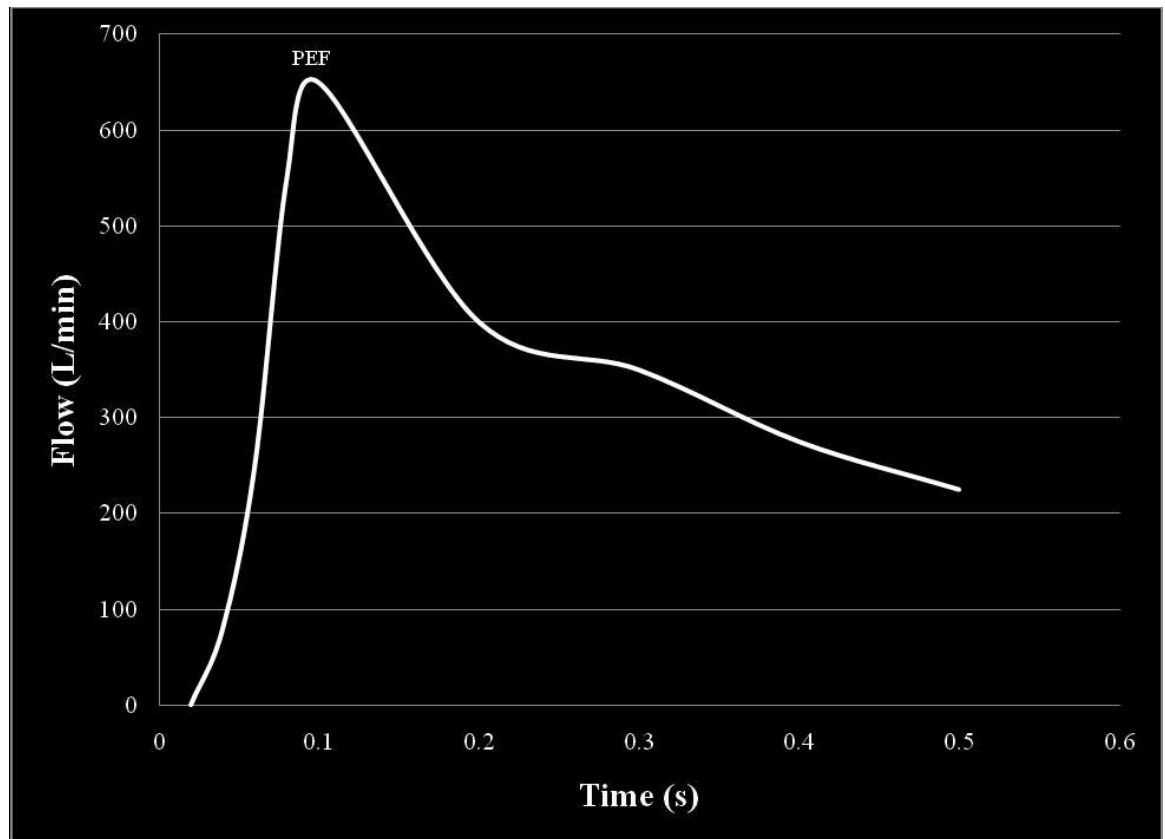


Figure 1—PEF waveform (representation only—does not correspond to real values)

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.

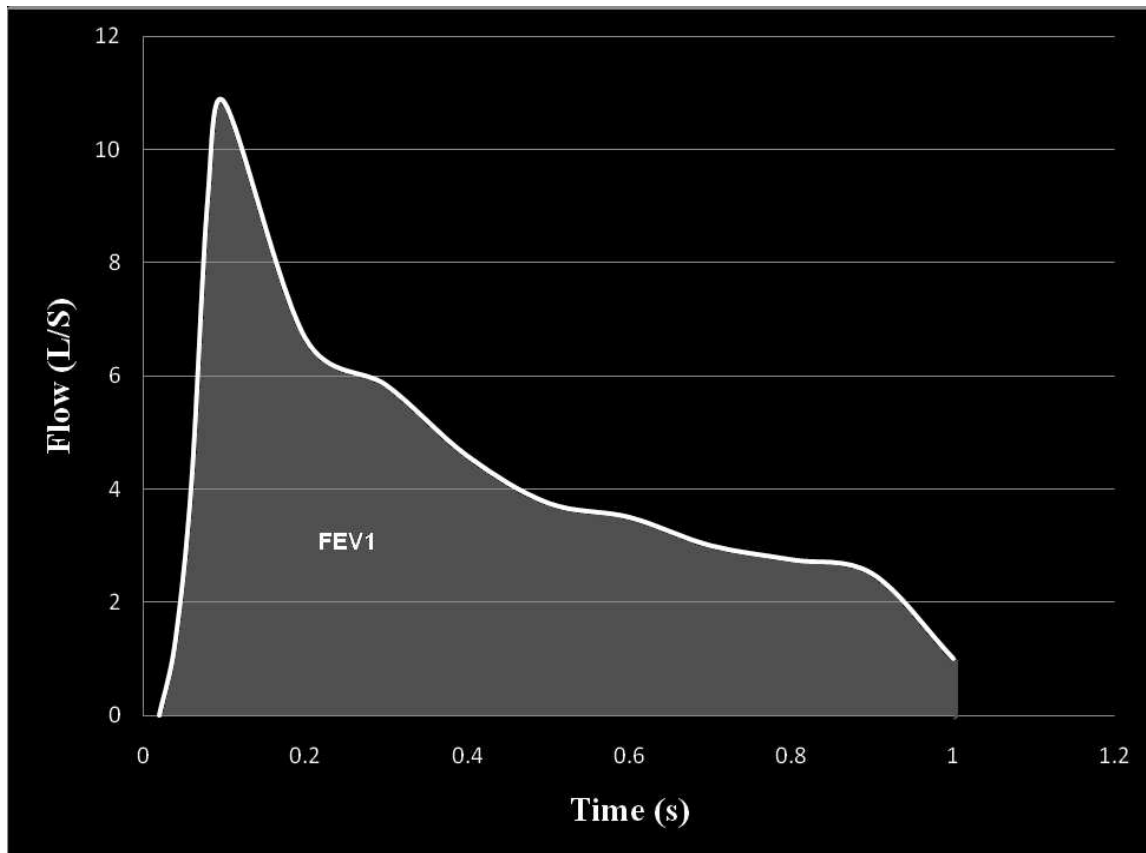


Figure 2—FEV1 waveform (representation only—does not correspond to real values)

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.

The objects of the DIM, as shown in Figure 3, are described in 6.5 through 6.10. This includes the medical device system (MDS) object (6.5), the numeric objects (6.6), the real-time sample array objects (6.7), the enumeration objects (6.8), the PM-store objects (6.9), and the scanner objects (6.10). Subclause 6.11 describes the rules for extending the peak expiratory flow monitor information model beyond elements as described in this standard. Each subclause that describes an object of the peak expiratory flow monitor contains the following information:

- The nomenclature code used to identify the class of the object. One example where this code is used is the configuration event, where the object class is reported for each object. This allows the manager to determine whether the class of the object being specified is a numeric, real-time sample array, enumeration, scanner, or PM-store class.
- The attributes of the object. Each object has attributes that represent and convey information on the physical device and its data sources. Each object has a Handle attribute that identifies the object instance within an agent. Attribute values are accessed and modified using methods such as GET and SET. Attribute types are defined using ASN.1. The ASN.1 definitions for new attribute types specific to this standard are in Annex B, and the ASN.1 definitions for existing attribute types referenced in this standard are in IEEE Std 11073-20601.
- The methods available on the object.
- The potential events generated by the object. The data are sent to the manager using events.
- The available services such as getting or setting attributes.

The attributes for each class are defined in tables that specify the name of the attribute, its value, and its qualifier. The qualifiers mean: M — Attribute is Mandatory, C — Attribute is Conditional and depends on the condition stated in the Remark or Value column (if IEEE Std 11073-20601 is referenced, then it contains the conditions), R — Attribute is Recommended, NR — Attribute is Not Recommended, and O — Attribute is Optional. Mandatory attributes shall be implemented by an agent. Conditional attributes shall be implemented if the condition applies and may be implemented otherwise. Recommended attributes should be implemented by the agent. Not recommended attributes should not be implemented by the agent. Optional attributes may be implemented by the agent.

The attributes can be either static, meaning that they shall remain unchanged after the configuration is agreed upon, or dynamic, meaning that the attribute may change at some point after configuration.

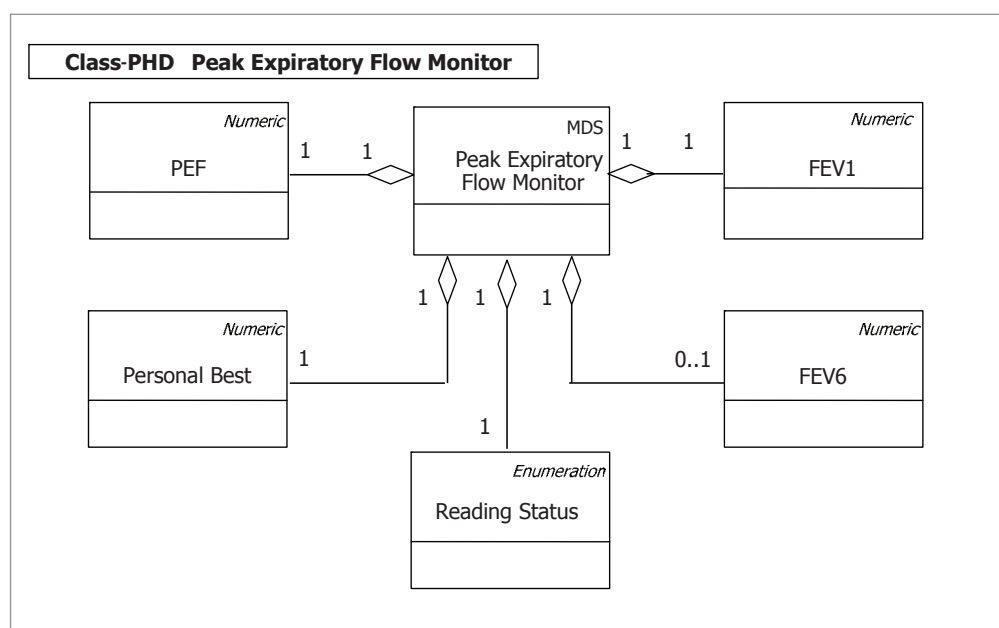


Figure 3—Peak expiratory flow monitor—domain information model

6.4 Types of configuration

6.4.1 General

As specified in IEEE Std 11073-20601, there are two styles of configuration available. Subclauses 6.4.2 and 6.4.3 briefly introduce standard and extended configurations.

6.4.2 Standard configuration

Standard configurations are defined in the IEEE 11073-104zz specializations (such as this standard) and are assigned a well-known identifier (Dev-Configuration-Id). The usage of a standard configuration is negotiated at association time between the agent and the manager. If the manager recognizes and selects to operate using the configuration, then the agent can send measurements immediately. If the manager does not recognize the configuration, the agent provides the configuration prior to transmitting measurement information.

6.4.3 Extended configuration

In extended configurations, the agent's configuration is not predefined in a standard. The agent determines the objects, attributes, and values that will be used in a configuration and assigns a configuration identifier. When the agent associates with a manager, an acceptable configuration is negotiated. Typically, the manager does not recognize the agent's configuration on the first connection, so the manager responds that the agent needs to send its configuration information as a configuration event report. If, however, the manager recognizes the configuration, either because it was preloaded in some way or the agent had previously associated with the manager, then the manager responds that the configuration is known and no further configuration information needs to be sent.

6.5 Medical device system object

6.5.1 MDS object attributes

Table 1 summarizes the attributes of the peak expiratory flow monitor MDS object. The nomenclature code to identify the MDS class is MDC_MOC_VMS_MDS_SIMP.

Table 1—MDS object attributes

Attribute name	Value	Qual.
Handle	0	M
System-Type	Attribute not present. See IEEE Std 11073-20601.	C
System-Type-Spec-List	{MDC_DEV_SPEC_PROFILE_PEFM, 1}.	M
System-Model	{“Manufacturer”, “Model”}.	M
System-Id	Extended unique identifier (64-bits) (EUI-64).	M
Dev-Configuration-Id	Standard config: 0x0834 (2100) Extended configs: 0x4000-0x7FFF.	M
Attribute-Value-Map	See IEEE Std 11073-20601.	C
Production-Specification	See IEEE Std 11073-20601.	O
Mds-Time-Info	See IEEE Std 11073-20601.	C
Date-and-Time	See IEEE Std 11073-20601.	C
Relative-Time	See IEEE Std 11073-20601.	C
HiRes-Relative-Time	See IEEE Std 11073-20601.	C
Date-and-Time-Adjustment	See IEEE Std 11073-20601.	C
Power-Status	<i>onBattery</i> or <i>onMains</i> .	O
Battery-Level	See IEEE Std 11073-20601.	O
Remaining-Battery-Time	See IEEE Std 11073-20601.	O
Reg-Cert-Data-List	See IEEE Std 11073-20601.	O
Confirm-Timeout	See IEEE Std 11073-20601.	O

NOTE—See IEEE Std 11073-20601 for information on whether an attribute is static or dynamic.

In the response to a Get MDS Object command, only implemented attributes and their corresponding values are returned.

See IEEE Std 11073-20601 for descriptive explanations of the individual attributes as well as for information on attribute ID and attribute type.

The Dev-Configuration-Id attribute holds a locally unique 16-bit identifier that identifies the device configuration. For a peak expiratory flow monitor agent with extended configuration, this identifier is chosen in the range of extended-config-start to extended-config-end (see IEEE Std 11073-20601) as shown in Table 1.

The agent sends the Dev-Configuration-Id during the Associating state (see 8.3) to identify its configuration for the duration of the association. If the manager already holds the configuration information relating to the Dev-Configuration-Id, it recognizes the Dev-Configuration-Id and the Configuring state (see 8.4) is skipped, and the agent and manager then enter the Operating state. If the manager does not recognize the Dev-Configuration-Id, the agent and manager enter the Configuring state.

If an agent implements multiple IEEE 11073-104zz specializations, System-Type-Spec-List is a list of type/version pairs, each referencing the respective device specialization and version of that specialization.

6.5.2 MDS object methods

Table 2 defines the methods (actions) of the MDS object. These methods are invoked using the Action service. In Table 2, the Subservice type name column defines the name of the method; the Mode column defines whether the method is invoked as an unconfirmed action (i.e., roiv-cmip-action from IEEE Std 11073-20601) or a confirmed action (i.e., roiv-cmip-confirmed-action); the Subservice type (action-type) column defines the nomenclature code to use in the action-type field of an action request and response (see IEEE Std 11073-20601); the Parameters (action-info-args) column defines the associated ASN.1 data structure (see IEEE Std 11073-20601 for ASN.1 definitions) to use in the action message for the action-info-args field of the request; and the Results (action-info-args) column defines the structure to use in the action-info-args of the response.