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## NATIONAL FOREWORD

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EUROPEAN STANDARD

EN ISO 11073-10421

NORME EUROPÉENNE

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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)

This European Standard was approved by CEN on 20 October 2012.

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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of an identical text or by endorsement, at the latest by May 2013, and conflicting national standards shall be withdrawn at the latest by May 2013.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

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## 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<sup>a</sup> 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.

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<sup>a</sup> For information on references, see Clause 2.

# Health informatics — Personal health device communication —

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

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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]<sup>1</sup> 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.<sup>2</sup>

## 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.<sup>3,4</sup>

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.

<sup>1</sup> The numbers in brackets correspond to those of the bibliography in Annex A.

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