# INTERNATIONAL STANDARD 11

### ISO/IEEE 11073-10415

First edition 2010-05-01

## Health informatics — Point-of-care medical device communication —

Part 10415: Device specialization — Weighing scale

Informatique de santé — Communication entre dispositifs médicaux sur le site des soins —

Partie 10415: Spécialisation des dispositifs — Plateau de balance

osilstandardsitehalla



#### PDF disclaimer

This PDF file may contain embedded typefaces. In accordance with Adobe's licensing policy, this file may be printed or viewed but shall not be edited unless the typefaces which are embedded are licensed to and installed on the computer performing the editing. In downloading this file, parties accept therein the responsibility of not infringing Adobe's licensing policy. Neither the ISO Central Secretariat nor IEEE accepts any liability in this area.

Adobe is a trademark of Adobe Systems Incorporated.

Details of the software products used to create this PDF file can be found in the General Info relative to the file; the PDF-creation parameters were optimized for printing. Every care has been taken to ensure that the file is suitable for use by ISO member bodies and IEEE members. In the unlikely event that a problem relating to it is found, please inform the ISO Central Secretariat or IEEE at the address given below.

Itell Standards tellad standards and standards sales sales so sales and standards and standards sales and sales and



#### COPYRIGHT PROTECTED DOCUMENT

© ISO 2010 © IEEE 2010

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either ISO or IEEE at the respective address below.

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
Published in Switzerland

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

| Contents   | Page |
|--|------|
| Foreword   | v    |
|  |      |
| Introduction   | V11  |
| 1. Overview  | 1    |
| 1.1 Coope  | 1    |
| 1.1 Scope  |      |
| 1.3 Context  |      |
|  |      |
| 2. Normative references  | 2    |
| 2. Normative references  3. Definitions, acronyms, and abbreviations  3.1 Definitions.  3.2 Acronyms and abbreviations.  4. Introduction to ISO/IEEE 11073 personal health devices.  4.1 General.  4.2 Introduction to IEEE 11073-20601 modeling constructs  5. Weighing scale device concepts and modalities.  5.1 General. |      |
|  |      |
| 3. Definitions, acronyms, and abbreviations  | 22   |
| 21 D. C. W. Sistle 2.10  | 2    |
| 3.1 Definitions.   | 2    |
| 3.2 Acronyms and appreviations   | 3    |
| 4. Introduction to ISO/IEEE 11073 personal health devices  | 3    |
| 4. Introduction to 150/1EEE 110/3 personal hearth devices  |      |
| 4.1 General  | 3    |
| 4.2 Introduction to IEEE 11073-20601 modeling constructs   | 4    |
| Kell W   |      |
| 5. Weighing scale device concepts and modalities   | 4    |
| dat 682  |      |
| 5.1 General  | 4    |
| 5.2 Body weight  | 5    |
| 5.3 Body height  | 5    |
| 5.1 General 5.2 Body weight 5.3 Body height 5.4 Body mass index  | 5    |
| 6. Weighing scale domain information model   | 5    |
| 6.1 Overview   | 5    |
| 6.2 Class extensions   |      |
| 6.3 Object instance diagram  |      |
| 6.4 Types of configuration   |      |
| 6.5 Medical device system object   |      |
| 6.6 Numeric objects  |      |
| 6.7 Real-time sample array objects   | 15   |
| 6.8 Enumeration objects  |      |
| 6.9 PM-store objects   |      |
| 6.10 Scanner objects   |      |
| 6.11 Class extension objects   |      |
| 6.12 Weighing scale information model extensibility rules  | 15   |
| 7. Weighing scale service model  | 15   |
| 7.1 General  | 15   |
| 7.2 Object access services   |      |
| 7.3 Object access event report services  |      |

#### ISO/IEEE 11073-10415:2010(E)

| 8.1 Overview 8.2 Communications characteristics. 8.3 Association procedure 8.4 Configuring procedure 8.5 Operating procedure 8.6 Time synchronization  9. Test associations  9.1 Behavior with standard configuration 9.2 Behavior with extended configurations  10.1 Applicability  |    |
|--|----|
| 8.2 Communications characteristics. 8.3 Association procedure. 8.4 Configuring procedure. 8.5 Operating procedure. 8.6 Time synchronization.  9. Test associations.  9.1 Behavior with standard configuration. 9.2 Behavior with extended configurations.  | 17 |
| 8.3 Association procedure 8.4 Configuring procedure 8.5 Operating procedure 8.6 Time synchronization  9. Test associations  9.1 Behavior with standard configuration 9.2 Behavior with extended configurations  10. Conformance  |    |
| 8.4 Configuring procedure 8.5 Operating procedure 8.6 Time synchronization  9. Test associations  9.1 Behavior with standard configuration 9.2 Behavior with extended configurations  10. Conformance  |    |
| 8.5 Operating procedure. 8.6 Time synchronization.  9. Test associations.  9.1 Behavior with standard configuration. 9.2 Behavior with extended configurations.  10. Conformance.  |    |
| 8.6 Time synchronization.  9. Test associations.  9.1 Behavior with standard configuration.  9.2 Behavior with extended configurations.  10. Conformance.  |    |
| 9.1 Behavior with standard configuration   |    |
| 9.2 Behavior with extended configurations.  10. Conformance  | 21 |
| 10. Conformance  | 22 |
|  | 22 |
| 10.1 A   | 22 |
| 10.1 Applicability   | 22 |
| 10.2 Conformance specification.  | 22 |
| 10.3 Levels of conformance   | 23 |
| 10.4 Implementation conformance statements   | 23 |
|  |    |
| Annex A (informative) Bibliography   | 28 |
| The Maria Lie 13.  |    |
| Annex B (normative) Any additional ASN.1 definitions   | 29 |
| De 18.1 id. udar eer   |    |
| Annex C (normative) Allocation of identifiers of the state of the stat | 30 |
| Allier C (normative) Anocation of normatives starting 218  | 50 |
| State Call Cate Collins of the Cate Call Cate Call Cate Call Call Cate Call Call Call Call Call Call Call Cal  | ۰. |
| Annex D (informative) Message sequence examples  | 31 |
| itely diff.  |    |
| Annex E (informative) Protocol data unit examples  | 33 |
| 10.1 Applicability. 10.2 Conformance specification. 10.3 Levels of conformance. 10.4 Implementation conformance statements.  Annex A (informative) Bibliography.  Annex B (normative) Any additional ASN.1 definitions.  Annex C (normative) Allocation of identifiers.  Annex D (informative) Message sequence examples.  Annex E (informative) Protocol data unit examples.  |    |

#### **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 11073-10415 was prepared by the 11073 Committee of the Engineering in Medicine and Biology Society of the IEEE (as IEEE Std 11073-10415-2008). 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

#### ISO/IEEE 11073-10415:2010(E)

- 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 Independent living activity hub
- Part 20101: (Point-of-care medical device communication) Application profiles Base standard
- a communication device — 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

© ISO 2010 - All rights reserved © IEEE 2010 - All rights reserved

#### Introduction

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<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.

IT ON STANDARD FREE STANDARDS STANDA

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

ITOH STANDARD RELIGIOUS AND STANDARD ST

### Health informatics — Point-of-care medical device communication —

Part 10415:

Device specialization — Weighing scale

IMPORTANT NOTICE: This standard is not intended to assure safety, security, health, or environmental protection in all circumstances. Implementers of the standard are responsible for determining appropriate safety, security, environmental, and health practices or regulatory requirements.

This IEEE document is made available for use subject to important notices and legal disclaimers. These notices and disclaimers appear in all publications containing this document and may be found under the heading "Important Notice" or "Important Notices and Disclaimers Concerning IEEE Documents." They can also be obtained on request from IEEE or viewed at http://standards.ieee.org/IPR/disclaimers.html.

#### 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 weighing scale devices and compute engines (e.g., cell phones, personal computers, personal health appliances, and 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 weighing scales.

#### 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, and set top boxes). Interoperability is the key to growing the potential market for these devices and to enabling people to be better informed participants in the management of their health.

#### 1.3 Context

See IEEE Std 11073-20601<sup>™</sup> for an overview of the environment within which this standard is written.

This document, IEEE Std 11073-10415, defines the device specialization for the weighing scale, 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, which in turn draws information from both ISO/IEEE 11073-10201:2004 [B4]<sup>1</sup> and ISO/IEEE 11073-20101:2004 [B5]. The medical device encoding rules (MDER) used within this standard are fully described in IEEE Std 11073-20601.

This standard reproduces relevant portions of the nomenclature found in ISO/IEEE 11073-10101:2004 [B3] and adds new nomenclature codes for the purposes of this standard. Between this standard and IEEE Std 11073-20601, all required nomenclature codes for implementation are documented.

NOTE— In this standard, IEEE Std 11073-104zz is used to refer to the collection of device specialization standards that utilize IEEE Std 11073-20601, 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<sup>™</sup>-2008, Health informatics—Personal health device communication—Part 20601: Application profile—Optimized Exchange Protocol.<sup>3,4</sup>

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* [B2] 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, it 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. handle:** An unsigned 16-bit number that is locally unique and identifies one of the object instances within an agent.

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

<sup>&</sup>lt;sup>2</sup> Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.

<sup>&</sup>lt;sup>3</sup>The IEEE standards or products referred to in this clause are trademarks of the Institute of Electrical and Electronics Engineers, Inc. <sup>4</sup>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 agent systems. Some examples of managers include a cellular phone, health appliance, set top box, or a computer system.
- **3.1.7. mass:** An intrinsic property of matter that can be measured using the effect of the gravitational field on an object.
- 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. personal health device:** A device used in personal health applications.
- 3.1.11. personal telehealth device: See: personal health device.
- **3.1.12. weight:** The force that results from the exertion of gravity on an object. The weight is directly proportional to the mass of the object. However, in the health care domain the term body weight is typically used to denote the body mass of a person. This notation applies also to this standard.

#### 3.2 Acronyms and abbreviations implementation conformance statement medical device encoding rules medical device system nanaged oh: **APDU** ASN.1 **BMI** DIM **EUI-64 ICS MDC MDER MDS** managed object class personal health device MOC real-time sample array virtual medical PHD RT-SA VMO **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 weighing scale device. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 PHD weighing scale 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) [B6]. Nomenclature codes referenced in this standard, which are not defined in ISO/IEEE 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.

#### 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. Weighing scale device concepts and modalities

#### 5.1 General

This clause presents the general concepts of weighing scale devices. In the context of personal health devices in this family of standards, a weighing scale is a device that measures the body weight of a person and, optionally, determines other physiological quantities (e.g., the body mass index or the height of a person). Weighing scale devices considered in this standard are typically placed on the floor with a person stepping on the device to perform a weight measurement, with the result being converted into mass internally of the device.

In the personal health context, the body weight of a person is typically not measured more frequently than twice a day.

Weighing scale devices may use a variety of techniques for measuring body weight. One typical method is to place several strain-gauge load cells under the measurement plane to convert deformation into weight.

#### 5.2 Body weight

The primary data type of a weighing scale device is body weight. It has measurement units of kilograms (kg) or pounds (lb).

#### 5.3 Body height

If body mass index reporting is supported, then body height is required. Body height denotes the actual height of the person using a weighing scale device. It has measurement units of centimeters (cm) or inches (in). This observation is typically entered manually.

#### 5.4 Body mass index

The body mass index (BMI) is a measure for indicating an overweight or underweight condition of a person and is defined as the individual's body weight, in kilograms, divided by the square of height, in meters (see Garrow and Webster [B1]):

BMI is not measured directly but is derived from body weight and body height. In the case where pounds and inches are used as measurement units instead of kilograms and meters, the BMI may be calculated as follows:

BMI = 
$$703 \times \frac{\text{body weight [lb]}}{\text{body height squared [in}^2]}$$

Using the value 703 as a conversion factor gives a relative error with respect to using kilograms and meters of less than 0.01%.

#### 6. Weighing scale domain information model

#### 6.1 Overview

This clause describes the domain information model of the weighing scale.

#### 6.2 Class extensions

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