INTERNATIONAL STANDARD

# ISO/IEEE 11073-10441

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# Health informatics — Personal health device communication —

## Part 10441: Device specialization — Cardiovascular fitness and activity monitor

*Informatique de santé — Communication entre dispositifs de santé personnels —*

*Partie 10441: Spécialisation des dispositifs — Moniteur d'activité et de forme cardiovasculaire*

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— *Part 00103: Overview*

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

— *Part 10102: (Point-of-care medical device communication) Nomenclature — Annotated ECG*

— *Part 10103: (Point-of-care medical device communication) — Nomenclature — Implantable device, cardiac*

— *Part 10201: (Point-of-care medical device communication) Domain information model*

— *Part 10404: Device specialization — Pulse oximeter*

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— *Part 10406: Device specialization — Basic electrocardiograph (ECG) (1- to 3-lead ECG)*

— *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 10418: Device specialization — International Normalized Ratio (INR) monitor*

— *Part 10420: Device specialization — Body composition analyzer*

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

— *Part 10441: Device specialization — Cardiovascular fitness and activity monitor*

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— *Part 10471: Device specialization — Independent 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*

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# Part 10441: Device specialization—Cardiovascular fitness and activity monitor

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29 March 2013

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**Health informatics—Personal health device communication**

# Part 10441: Device specialization—Cardiovascular fitness and activity monitor

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**Abstract:** Within the context of the ISO/IEEE 11073 family of standards for device communication, a normative definition of communication between personal telehealth cardiovascular fitness and activity monitor devices and managers (e.g., cell phones, personal computers, personal health appliances, and set top boxes) is established in this standard in a manner that enables plug-and-play interoperability. Appropriate portions of existing standards are leveraged including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards. The use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability is specified. A common core of communication functionality for personal telehealth cardiovascular fitness and activity monitor devices is defined in this standard.
**Keywords:** activity monitor, cardiovascular fitness, IEEE 11073-10441™, medical device communication, personal health devices

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# Introduction

This introduction is not part of IEEE Std 11073-10441-2013, IEEE Standard for Health informatics—Personal health device communication—Device specialization—Cardiovascular fitness and activity monitor.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. This document uses the optimized framework created in IEEE Std 11073-20601a™-2010[a] and describes a specific, interoperable communication approach for cardiovascular fitness and activity monitors. These standards align with, and draw on, the existing clinically focused standards to provide easy management of data from either a clinical or a personal health device.

[a] Information on references can be found in Clause 2.


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## Health informatics—Personal health device communication

# Part 10441: Device specialization—Cardiovascular fitness and activity monitor

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## 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 the communication between personal cardiovascular fitness and activity monitoring devices 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 appropriate portions of existing standards including ISO/IEEE 11073 terminology and information models. 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 cardiovascular fitness and activity monitor devices. In this context, cardiovascular fitness and activity monitor devices are being used broadly to cover cardiovascular fitness and activity monitor devices that measure physical actions and the body's various physiological responses to that activity.



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## 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 managers (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 11073-20601a-2010[1] for an overview of the environment within which this standard is written.

This document defines the device specialization for the cardiovascular fitness and activity 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 11073-20601a-2010 and ISO/IEEE 11073-20601:2010(E), which in turn draw information from both ISO/IEEE 11073-10201:2004 [B7] and ISO/IEEE 11073-20101:2004 [B8].[2] The medical device encoding rules (MDERs) used within this standard are fully described in ISO/IEEE 11073-20601:2010(E).

This standard reproduces relevant portions of the nomenclature found in ISO/IEEE 11073-10101:2004 [B6] and adds new nomenclature codes for the purposes of this standard. Between this standard, ISO/IEEE 11073-20601:2010(E), and IEEE Std 11073-20601a-2010, all required nomenclature codes for implementation are documented.

NOTE 1—IEEE Std 11073-20601a-2010 is an amendment to ISO/IEEE 11073-20601:2010(E). It contains new material and corrections and does not copy the content of ISO/IEEE 11073-20601:2010(E). Throughout this standard, a reference to IEEE Std 11073-20601a-2010 refers to the document that is obtained after applying this new material and corrections to ISO/IEEE 11073-20601:2010(E).[3]

NOTE 2— In this standard, ISO/IEEE P11073-104zz is used to refer to the collection of device specialization standards that utilize IEEE Std 11073-20601a-2010, where zz can be any number from 01 to 99, inclusive.

# 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 11073-20601a™-2010, Health informatics—Personal health device communication—Application profile—Optimized Exchange Protocol—Amendment 1.[4,5]

ISO/IEEE 11073-20601:2010(E), Health informatics—Personal health device communication—Application profile—Optimized Exchange Protocol.[6]

[1] Information on references can be found in Clause 2.
[2] The numbers in brackets correspond to those of the bibliography in Annex A.
[3] Notes in text, tables, and figures of a standard are given for information only and do not contain requirements needed to implement this standard.
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See Annex A for all informative material referenced by this standard.

# 3. Definitions, acronyms, and abbreviations

## 3.1 Definitions

For the purposes of this document, the following terms and definitions apply. The *IEEE Standards Dictionary Online* should be consulted for terms not defined in this clause.[7]

**agent:** A node that collects and transmits personal health data to an associated manager.

**class:** In object-oriented modeling, a class describes the attributes, methods, and events that objects instantiated from the class utilize.

**device:** A term used to refer to a physical apparatus implementing either an agent or a manager role.

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

**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.

**mass:** An intrinsic property of matter that can be measured using the effect of the gravitational field on an object.

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

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

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

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

**proportional integral mode (PIM):** This mode is defined as the integral of a variable with respect to one of its axes over the duration of the session or subsession. It is used in actigraphy to provide an activity measurement.

**root mean square (RMS):** The square root of the average of the squares of a variable over the duration of the session or subsession.

**time above threshold (TAT):** This is defined as the total time that an input variable exceeds a given threshold value over the duration of the session or subsession. It is used in actigraphy to provide an activity measurement.

**weight:** The force that results from the exertion of gravity on an object. The weight is directly propotional to the mass of the object**.** However, in the healthcare domain, the term “body weight” is typically used to denote the body mass of a person. This notation applies also to this standard.

---

[6] ISO/IEC publications are available from the ISO Central Secretariat (http://www.iso.org/). ISO publications are also available in the United States from the American National Standards Institute (http://www.ansi.org/).

[7] The *IEEE Standards Dictionary Online* subscription is available at http://www.ieee.org/portal/innovate/products/standard/standards_dictionary.html.



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## 3.2 Acronyms and abbreviations

| | |
|---|---|
| 2D | two-dimensional |
| 3D | three-dimensional |
| APDU | application protocol data unit |
| ASN.1 | Abstract Syntax Notation One |
| DIM | domain information model |
| ICS | implementation conformance statement |
| MDC | medical device communication |
| MDS | medical device system |
| MOC | managed object class |
| PHD | personal health device |
| PIM | proportional integral mode |
| RPM | revolutions per minute |
| RMS | root mean square |
| RT-SA | real-time sample array |
| TAT | time above threshold |
| 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 healthcare information systems. See IEEE Std 11073-20601a-2010 for a description of the guiding principles for this series of ISO/IEEE 11073 Personal Health Device standards.

IEEE Std 11073-20601a-2010 supports the modeling and implementation of an extensive set of personal health devices (PHDs). This standard defines aspects of the cardiovascular fitness and activity monitor device. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 PHD cardiovascular fitness and activity monitor agent and a manager. This standard defines a subset of the objects and functionality contained in IEEE Std 11073-20601a-2010 and extends and adds definitions where appropriate. All new definitions are given in Annex B in Abstract Syntax Notation One (ASN.1) (ITU-T Rec. X.680-2002 [B9]). Nomenclature codes referenced in this standard, which are not defined in IEEE Std 11073-20601a-2010, are normatively defined in Annex C.

## 4.2 Introduction to ISO/IEEE 11073-20601 modeling constructs

### 4.2.1 General

The ISO/IEEE 11073 series of standards, and in particular IEEE Std 11073-20601a-2010, 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 11073-20601a-2010 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


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agent can communicate to a manager. Communication between the agent and the manager is defined by the application protocol in IEEE Std 11073-20601a-2010.

### 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 11073-20601a-2010 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 11073-20601a-2010.

### 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.

## 4.3 Compliance with other standards

Devices that comply with this standard may also be required to comply with other domain and device specific standards that supersede the requirements of this standard with respect to issues including safety, reliability, and risk management. A user of this standard is expected to be familiar with all other such standards that apply and to comply with any higher specifications thus imposed. Typically, medical devices will comply with the IEC 60601-1:2005 [B1] base standards with respect to electrical and mechanical safety and any device specific standard as might be defined in the IEC 60601-2 series of standards [B2]. Software aspects may apply through standards such as IEC 62304:2006/EN 62304:2006 [B3]. Devices that comply with this standard implement higher layers of network software and utilize lower layers as appropriate to the application. The requirements on performance of such applications and conformance are defined elsewhere and are outside the scope of this standard. Moreover, the use of any medical equipment is subject to risk assessment and risk management appropriate to the application. Some relevant examples are ISO 14971:2007 [B5] and IEC 80001-1:2010 [B4]. The requirements of such risk assessment and risk management and conformance are outside the scope of this standard.

# 5. Cardiovascular fitness and activity monitor device concepts and modalities

Cardiovascular fitness and activity monitor agents measure the physical activity of an individual and record the physiological response to that activity. Agents include treadmills, exercise bikes, heart rate monitors, bike computers, pedometers, and overall activity/lifestyle monitors. Although there is great variety in the forms of these agents, there is significant commonality and overlap in the measurements they make.


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## 5.1 General concepts

Agents in this category typically measure activity over a period of time called a session (see 6.9.4 for details).

One mode of operations is to provide session summaries once a session is closed. The data associated with a session may vary greatly from agent to agent. Minimally, the session will include information about the date and time of the session, as well as the session duration and the activity that was measured during the session. In addition, there may be a variety of metrics calculated for the entire session, like total distance or mean speed. In some agents, the concept of subsessions is important. These subsessions provide a mechanism to break up a session into smaller components that represent specific periods within the session. The primary example of this is the lap concept, where an agent may allow users to mark when they have completed a lap to be more granular in their data organization. Like a session, subsessions may have a variety of metrics that apply across the entire subsession, reporting either the mean, maximum, or minimum values over the session/subsession (i.e., subsession distance and mean speed).

Another mode of operations is to perform continuous monitoring while sessions and subsessions are in progress; this is to collect metrics either periodically or episodically or both along with their timestamps at a given sampling period. This allows applications to display progress during sessions and subsessions.

Raw data that are generated at much higher frequencies (maybe hundreds of time per second) can also be collected though continuous monitoring sessions and transmitted to the manager without information loss. This type of data requires the use of special ISO/IEEE 20601 metrics known as real-time sample array (RT-SA) objects and is restricted to periodic.

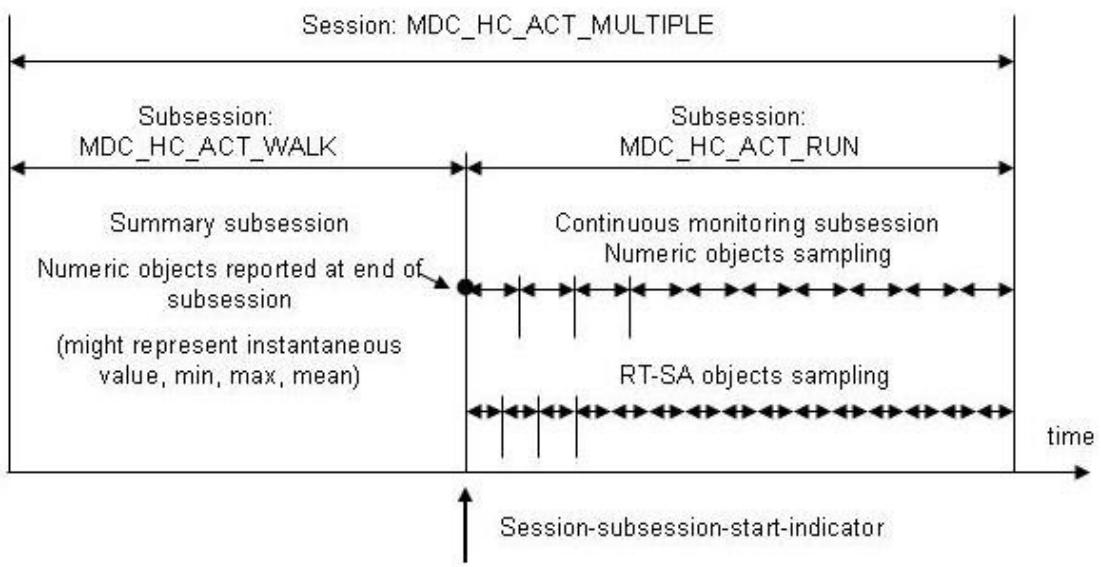


**Figure 1—Sessions, subsessions, and their sampling rates**

Figure 1 provides an illustration of the sessions, subsessions, and their different methods of reporting data. In this example, a multiple session is made of a walking subsession followed by a running subsession. The first subsession is a summary subsession providing a single point of measurement at the end of the subsession. This data point might represent the instantaneous value, the minimum, the maximum, or the average value of objects. The second subsession is started with the session-subsession-start-indicator marking a continuously monitoring subsession where data are reported periodically. As such, one set of measurements (such as the heart rate) is sampled at a given frequency using ISO/IEEE 20601 numeric


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metric objects, while a second set of measurements (such as accelerometer data) RT-SA objects might be sampled at another much higher frequency using ISO/IEEE 20601 RT-SA objects.

Session summaries are used in the pedometer profile (see Clause 11), whereas session continuous monitoring are mandatory for the activity monitor profile (see Clause 12).

In 5.2 through 5.39, objects are presented in alphabetical order to allow an easy navigating of the document.

## 5.2 3D Acceleration (RT-SA)

Three-dimensional (3D) vector components (X, Y, Z, and Z-with-gravity-offset) of raw accelerometer sensory data. One vector is generated at each clock sample of the accelerometer. These components might be used to construct a two-dimensional (2D) or 3D vector in a scanner. Raw data are sometimes processed within devices like pedometers for fine trajectory calculation, spent energy, and so on. In some cases, these data are sent to the manager for further processing.

## 5.3 3D Angular acceleration (RT-SA)

3D vector components (X, Y, and Z), respectively, for pitch, roll, and yaw of raw angular accelerometer sensor (e.g., gyroscopes). One vector is generated at each clock sample of the gyroscope. These components might be used to construct a 2D or 3D vector in a scanner. Raw data are sometimes processed within devices like gaming remote controls or activity monitors for fine trajectory calculation, stabilization, and so on. In some cases, these data are sent to the manager for further processing.

## 5.4 Activity intensity (numeric)

This measurement reports the intensity of a certain activity. It is expected to be used as a supplement to the program identifier to describe the nature of the activity (e.g., slow running, moderate running, or fast running). The intensity of activity reports a percentage of intensity of this particular activity as compared with the top performance intensity. Calculation methods are known in the state of the art, e.g., running 70% could mean to run at 70% of the Vo2Max (maximum effort) capability, which can be approximated by the following formula:

$$\text{Vo2Max} = \text{Maximum recommended heart rate} \times 0.70$$

For calculation of the maximum recommended heart rate, see 5.25.

## 5.5 Activity time (enumeration)

This concept differs from a session or subsession in that this concept provides categorization and aggregation of the time spent in certain activities within the associated session or subsession. Typically, this concept is employed in general daily activity monitoring where daily activities are categorized by how much time in the session or subsession was spent in various activities such as sleeping, sitting, or walking.

## 5.6 Age (numeric)

Age is a setting typically entered manually by the user. The age setting might be used by an agent for derived calculations (e.g., calculation of maximum recommended heart rate; see 5.25).



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## 5.7 Altitude (numeric)

Altitude represents a point of elevation, relative to sea level.

## 5.8 Altitude gain (numeric)

While ascent time and distance (see 5.10) capture the distance and time spent gaining altitude, the measurement of altitude gain depicts the cumulative height gained during ascents since the start of a session or subsession.

If in Figure 2 a person traveled a→b→c, then both the altitude gain and the altitude loss would be bd. These values are equal because the start and finish for the route of travel are on the same elevation. However, if a person traveled from a→b, then the altitude gain would be bd and the altitude loss would be zero.

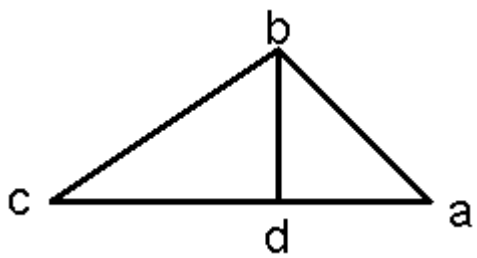


**Figure 2—Distance and elevation profile**

## 5.9 Altitude loss (numeric)

While descent time and distance (see 5.7) capture the distance and time spent losing altitude, the measurement of altitude loss depicts the cumulative height lost during descents since the start of a session or subsession.

If in Figure 2 a person traveled a→b→c, then both the altitude gain and the altitude loss would be bd. These values are equal because the start and finish for the route of travel are on the same elevation. However, if a person traveled from a→b, the altitude gain would be bd and the altitude loss would be zero.

## 5.10 Ascent time and distance

The ascent time records the period spent gaining elevation since the start of a session or subsession and may be used to determine a measure of work expended. The ascent distance records the respective distances covered during those periods.

If in Figure 2 a person traveled a→b→c, then the ascent distance would be ab and the descent distance would be bc.



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## 5.11 Body height (numeric)

Body height is a setting typically entered manually by the user. The height setting might be used by an agent for derived calculations (e.g., calculation of body mass index).

## 5.12 Body weight (numeric)

Body weight is a setting typically entered manually by the user, although an agent may have the capability to measure this directly. The weight setting might be used by an agent for derived calculations (e.g., calculation of the energy expended during a jogging session).

## 5.13 Breathing rate (numeric)

The breathing rate can provide information on lung function in response to physical exertion. The breathing rate can either be calculated as the maximum, minimum, or mean values for a session or subsession or as an instantaneous value.

## 5.14 Cadence (numeric)

Cadence records the frequency of a repetitive action, such as the rate of revolution of the pedals of a bicycle or striding frequency of a runner or walker. Cadence is either recorded as the minimum, mean, or maximum values for a session or subsession or as an instantaneous value.

## 5.15 Calories ingested (numeric)

Calories ingested are an entry, either through manual means or through an agent having the capability to set it. This is the number of calories consumed or ingested by a person since the start of a session or subsession.

## 5.16 Carbohydrate calories ingested (numeric)

Carbohydrate calories ingested are an entry, either through manual means or through an agent having the capability to set it. This is the number of carbohydrate calories consumed or ingested by a person since the start of a session or subsession.

## 5.17 Descent time and distance (numeric)

The descent time records the period spent losing elevation since the start of a session or subsession and may be used to determine a measure of work expended. The descent distance records the respective distances covered during those periods.

If in Figure 2 a person traveled a→b→c, then the ascent distance would be ab and the descent distance would be bc.

## 5.18 Distance (numeric)

Distance defines the total distance covered since the start of a session and/or subsession. Distance may be specified as the actual distance such as meters or feet, or in more abstract concepts such as steps taken or flights of stairs climbed. In the latter case, the distance expressed in MDC_DIM_STEP is equivalent to a stride count measurement.



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Using the distance and elevation profile shown in Figure 2 if a person were to travel a→b→c, the distance traveled would be ab + bc.

## 5.19 Energy expended (numeric)

This is the amount of energy expended since the start of a session or subsession.

## 5.20 Estimated weight loss (numeric)

The estimated weight loss approximates the weight loss since the start of a session and/or subsession. Weight loss is a common goal for cardiovascular exercise. It is typically calculated by step counters and activity monitors as a derivation from energy expended. The state of the art reports several methods of calculation based on energy expended and weight.

## 5.21 Heart rate (numeric)

Heart rates can be observed either as the maximum, minimum, or mean values for a session or subsession, or as an instantaneous value. The rate is a key indicator of physical exertion. In particular, the maximum observed heart rate is an important observation that might be used to calculate the VO2 of a user.

## 5.22 Incline (numeric)

This measurement represents the steepness of the incline being traveled either as a minimum, mean, or maximum value over a session or subsession or as an instantaneous value. A positive value means an incline and a negative one a decline. As such, the minimum incline gives the value of the steepest decline during the session or subsession.

## 5.23 Latitude (numeric)

This is the latitudinal (north/south) location of the person at a point in time.

## 5.24 Longitude (numeric)

This is the longitudinal (east/west) location of the person at a point in time.

## 5.25 Maximum recommended heart rate (numeric)

The maximum recommended heart rate is typically manually entered by the user (or the physician) or can be calculated. Its simplest estimation is given by the formula:

Maximum recommended heart rate = 220 – Age

The maximum recommended heart rate can be useful in providing context for the other values like the maximum, minimum, and mean observed heart rates achieved during an exercise session.

## 5.26 Proportional integral mode (PIM) (numeric)

PIM is defined for a session or subsession as the integral of the 3D variable with respect to one of its axes over the duration of the session or subsession. It is used in actigraphy to provide an activity measurement


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for both sleep and activity periods. Figure 3 shows an example for the PIM for the *z* axis for 3D acceleration.

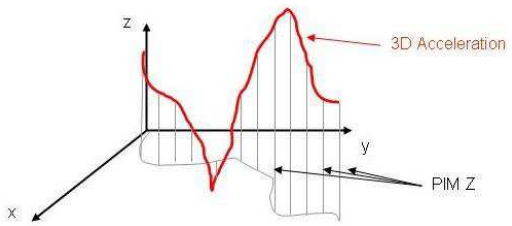


**Figure 3—Proportional integral mode (monodimentional z)**

Note that this PIM is not the one commonly defined by the IEEE in control systems as proportional integral mode.

## 5.27 Power (numeric)

Power is a measure of the work rate of a user. Power is measured either as a minimum, mean, and maximum value over a session or subsession or as an instantaneous value.

## 5.28 Program identifier (enumeration)

This measurement identifies the exercise program used by the person during a session or subsession.

## 5.29 Resistance (numeric)

This measurement represents either the minimum, mean, or maximum resistance employed over a session or subsession or the instantaneous resistance. This measurement applies primarily to machines that apply variable resistance to a person doing an exercise.

## 5.30 Root mean square (RMS) (numeric)

RMS is defined for a session or subsession as the root mean squared of the 3D variable with respect to one of its axes over the duration of the session or subsession.

## 5.31 Session (enumeration)

A session defines the envelope that contains all the measurements associated with an episode of activity/exercise. Each session defines its start date and time of the episode as well as the duration and the activity that the user engaged in during the episode.

## 5.32 Session-subsession-start-indicator (enumeration)

The session-subsession-start-indicator is used to mark the beginning of a continuously monitored session or subsession.


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## 5.33 Slopes (numeric)

This is the number of slopes skied by a person since the start of the session or a subsession.

## 5.34 Speed (numeric)

Speed adds additional context to the work being done and is used to capture how fast the user moved across a distance (5.18). Speed is either reported as minimum, mean, or maximum speed for a session or subsession or as instantaneous speed.

## 5.35 Stride length (numeric)

This is a measurement of the distance covered in a single stride/step when walking or running. It is either captured as a minimum, mean, and maximum value over a session or subsession or as an instantaneous value.

## 5.36 Subsession (enumeration)

The subsession defines the envelope that contains all the measurements associated with a portion of the session. Each subsession defines its start date, start time, and duration; it also contains the activity that the user engaged in during the subsession.

## 5.37 Sustained physical activity threshold (numeric)

This setting represents the amount of time a person must be engaged in physical activity to be considered sustained physical activity, which is an important metric in determining a person's activity level.

## 5.38 Time above threshold (TAT) (numeric)

TAT is defined for a session or subsession as the total time that the input variable exceeds a given threshold value over the duration of the session or subsession. Figure 4 shows an example for the TAT for the *z* axis for 3D acceleration.

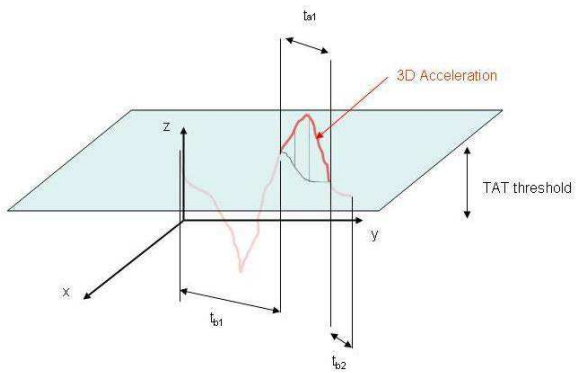


**Figure 4—Time above threshold (monodimensional *z*)**


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### 5.39 TAT-threshold (numeric)

The TAT-threshold is the value applied in evaluating the corresponding the TAT value. The TAT-threshold may change between sessions or subsession; in which case, the TAT-threshold should be provided with every TAT value.

## 6. Cardiovascular fitness and activity monitor domain information model

### 6.1 Overview

This clause describes the domain information model of the cardiovascular fitness and activity monitor.

### 6.2 Class extensions

In this standard, no class extensions are defined with respect to IEEE Std 11073-20601a-2010.

### 6.3 Object instance diagram

The object instance diagram of the cardiovascular fitness and activity monitor domain information model, defined for the purposes of this standard, is shown in Figure 5.

The objects of the DIM, as shown in Figure 5, are described in 6.4 through 6.13. This includes the medical device system (MDS) object (see 6.4), the numeric objects (see 6.7), the RT-SA objects (see 6.8), the enumeration objects (see 6.9), the PM-store objects (see 6.10), and the scanner objects (see 6.11). See 6.12 for rules for extending the information model beyond elements as described in this standard. Each subclause that describes an object of the cardiovascular fitness and activity 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 class, enumeration, scanner, or PM-store class.

— The attributes of the object. Each object has attributes that represent and convey information on the physical agent 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 communication services such as GET and SET. Attributes 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 in IEEE Std 11073-20601a-2010.

— 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 11073-20601a-2010 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.


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Not recommended attributes should not be implemented by the agent. Optional attributes may be implemented by the agent. For attributes with qualifiers set to R or NR, underlying requirements stated in the Remark and Value column in IEEE Std 11073-20601a-2010 shall be followed.

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.

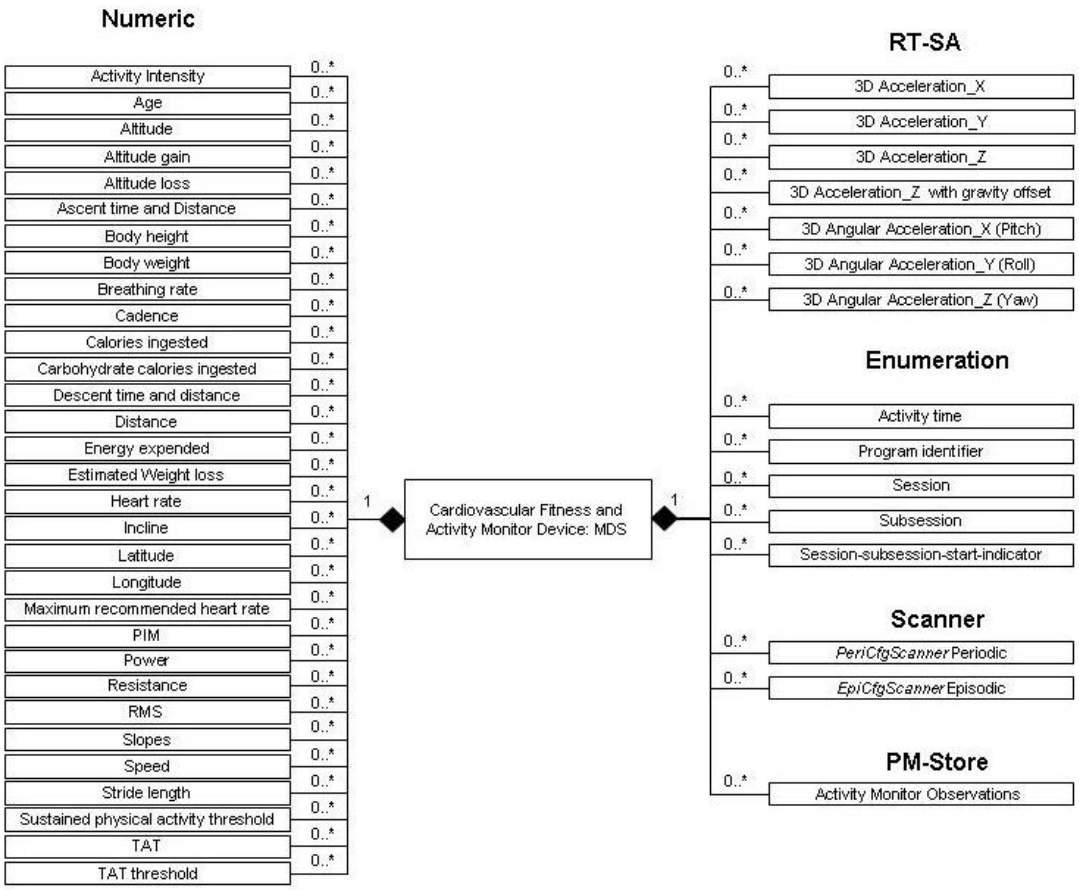


**Figure 5—Object instance diagram**

## 6.4 Types of configuration

### 6.4.1 General

As specified in IEEE Std 11073-20601a-2010, two styles of configuration are 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 ISO/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, then the agent provides the configuration prior to transmitting measurement information. This standard does not support standard configurations.


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### 6.4.3 Extended configuration

In extended configurations, the agent's configuration is not predefined in a standard. The agent determines which objects, attributes, and values that it wants to use in a configuration and assigns a configuration identifier. When the agent associates with a manager, it negotiates an acceptable configuration. Typically, the manager does not recognize the agent's configuration on the first connection, so the manager responds that the agent must send its configuration information as a configuration event report. If, however, the manager already understands 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 Profiles

### 6.5.1 General

A profile further constrains the objects, services, and communication model of a specialization. By profiling the device specialization, the standard provides more guidance on the specific mandatory objects that shall be implemented, for that profile. This standard defines two profiles: step counter (see Clause 11) and activity monitor (see Clause 12). A cardiovascular fitness and activity monitor device may implement one of these profiles.

## 6.6 Medical device system object

### 6.6.1 MDS object attributes

Table 1 summarizes the attributes of the cardiovascular fitness and activity monitor MDS object. The nomenclature code to identify the MDS object 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 11073-20601a-2010. | C |
| System-Model | {"Manufacturer","Model"}. | M |
| System-Id | See IEEE Std 11073-20601a-2010. | M |
| Dev-Configuration-Id | Extended configs: 0x4000-0x7FFF. | M |
| Attribute-Value-Map | See IEEE Std 11073-20601a-2010. | C |
| Production-Specification | See IEEE Std 11073-20601a-2010. | O |
| Mds-Time-Info | See IEEE Std 11073-20601a-2010. | C |
| Date-and-Time | See IEEE Std 11073-20601a-2010. | C |
| Relative-Time | See IEEE Std 11073-20601a-2010. | C |
| HiRes-Relative-Time | See IEEE Std 11073-20601a-2010. | C |
| Base-Offset-Time-Stamp | See IEEE Std 11073-20601a-2010. | C |
| Date-and-Time-Adjustment | See IEEE Std 11073-20601a-2010. | C |
| Power-Status | *onBattery* or *onMains*. | R |
| Battery-Level | See IEEE Std 11073-20601a-2010. | R |
| Remaining-Battery-Time | See IEEE Std 11073-20601a-2010. | R |
| Reg-Cert-Data-List | See IEEE Std 11073-20601a-2010. | O |
| System-Type-Spec-List | {MDC_DEV_SPEC_PROFILE_HF_CARDIO, 1}.<br>and Profile value:<br>{MDC_DEV_SUB_SPEC_PROFILE_STEP_COUNTER, 1} or<br>{MDC_DEV_SUB_SPEC_PROFILE_ACTIVITY, 1} | M |
| Confirm-Timeout | See IEEE Std 11073-20601a-2010. | O |

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


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See IEEE Std 11073-20601a-2010 for descriptive explanations of the individual attributes as well as for information on attribute ID and attribute type.

If an agent implements multiple ISO/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. For a cardiovascular fitness and activity monitor agent, a specialization value of MDC_DEV_SPEC_PROFILE_HF_CARDIO shall be included in the System-Type-Spec-List attribute as shown in Table 1. Additionally, the value(s) for the supported profile(s) shall be included in the System-Type-Spec-List attribute.

The Dev-Configuration-Id attribute holds a locally unique 16-bit identifier that identifies the device configuration. For a cardiovascular fitness and activity monitor agent, this identifier is chosen in the range of extended-config-start to extended-config-end (see IEEE Std 11073-20601a-2010) as shown in Table 1. Since it is an extended configuration, the actual configuration associated with the Dev-Configuration-Id is globally unique only for a given System-Id (agent device).

The agent sends the Dev-Configuration-Id and System-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 and System-Id pair, then it recognizes the Dev-Configuration-Id for that agent device. Then, the Configuration state (see 8.4) is skipped, and the agent and manager enter the Operating state. If the manager does not recognize the Dev-Configuration-Id for that System-Id, then the agent and manger enter the Configuring state.

If an agent implements multiple IEEE 11073-104zz specializations, then the System-Type-Spec-List will contain a list of type/version pairs each referencing the respective device specialization and version of that specialization in addition to the entry required for this specialization as noted in Table 1.

### 6.6.2 MDS object methods

Table 2 defines the methods (actions) of the cardiovascular fitness and activity monitor agent's 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 11073-20601a-2010) 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 11073-20601a-2010); the Parameters (action-info-args) column defines the associated ASN.1 data structure (see IEEE Std 11073-20601a-2010 and 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.

**Table 2—MDS object methods**

| Service | Subservice type name | Mode | Subservice type (action-type) | Parameters (action-info-args) | Results (action-info-args) |
|---|---|---|---|---|---|
| ACTION | Set-Time | Confirmed | MDC_ACT_SET_TIME | SetTimeInvoke | — |
| | Set-Base-Offset-Time | Confirmed | MDC_ACT_SET_BO_TIME | SetBOTimeInvoke | — |

*Set-Time*

This method allows the manager to set a real-time clock in the agent with the absolute time. The agent indicates whether the Set-Time command is valid using the mds-time-capab-set-clock bit in the Mds-Time-Info attribute (see IEEE Std 11073-20601a-2010).

If the agent supports the Absolute-Time-Stamp attribute, then this method shall be implemented.


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*Base-Offset-Time*

This method allows the manager to set a real-time clock in the agent with the base time and offset. The agent indicates whether the Set-Base-Offset-Time command is valid using the mds-time-capab-set-clock bit in the Mds-Time-Info attribute (see IEEE Std 11073-20601a-2010).

If the agent supports the Base-Offset-Time-Stamp attribute, then this method shall be implemented.

An agent may support either absolute time or base time, but not both. The time option used is indicated by the agent in the Mds-Time-Info attribute.

Agents following this device specialization shall support the sending of any temporarily stored and real-time measurement data using the agent-initiated method of measurement data transmission. This requirement does not prevent the agent from supporting additional methods of measurement data transmission, but agents that choose to support these additional methods shall fall back to the agent-initiated method of measurement data transmission when associated with a manager that does not support these additional methods of data transmission. During the association procedure (see 8.3), DataReqModeCapab shall be set to the appropriate value for the event report style. Managers supporting this specialization are only required to support agent-initiated measurement transfers. Thus, implementation of the MDS-Data-Request method/action is not required in this standard and is not shown in Table 2.

### 6.6.3 MDS object events

Table 3 defines the events that can be sent by the cardiovascular fitness and activity monitor MDS object.

**Table 3—MDS object events**

| Service | Subservice type name | Mode | Subservice type (event-type) | Parameters (event-info) | Results (event-reply-info) |
|---|---|---|---|---|---|
| EVENT REPORT | MDS-Configuration-Event | Confirmed | MDC_NOTI_CONFIG | ConfigReport | ConfigReportRsp |
| | MDS-Dynamic-Data-Update-Var | Confirmed | MDC_NOTI_SCAN_REPORT_VAR | ScanReportInfoVar | — |
| | MDS-Dynamic-Data-Update-Fixed | Confirmed | MDC_NOTI_SCAN_REPORT_FIXED | ScanReportInfoFixed | — |
| | MDS-Dynamic-Data-Update-MP-Var | Confirmed | MDC_NOTI_SCAN_REPORT_MP_VAR | ScanReportInfoMPVar | — |
| | MDS-Dynamic-Data-Update-MP-Fixed | Confirmed | MDC_NOTI_SCAN_REPORT_MP_FIXED | ScanReportInfoMPFixed | — |

— **MDS-Configuration-Event:**
This event is sent by the agent during the configuring procedure if the manager does not already know the agent's configuration from past associations. The event provides static information about the supported measurement capabilities of the agent.

— **MDS-Dynamic-Data-Update-Var:**
This event provides dynamic measurement data from the agent. These data are reported using a generic attribute list variable format. The event is sent as an unsolicited message by the agent


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