

# INTERNATIONAL STANDARD ISO/IEEE 11073-20601:2016 TECHNICAL CORRIGENDUM 1

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# Health informatics — Personal health device communication Part 20601: Application profile — Optimized exchange protocol

TECHNICAL CORRIGENDUM 1

Informatique de santé — Communication entre dispositifs de santé personnels — Partie 20601: Profil d'application — Protocole d'échange optimisé

RECTIFICATIF TECHNIQUE 1

Technical Corrigendum 1 to ISO/IEEE 11073-20601 was prepared by the IEEE 11073 Standards Comittee of the IEEE Engineering in Medicine and Biology Society (as IEEE Std 11073-20601-2014/Cor 1:2015). It was adopted by Technical Committee ISO/TC 215, *Health informatics*, in parallel with its approval by the ISO member bodies, under the "fast-track procedure" defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE. IEEE is responsible for the maintenance of this document with participation and input from ISO member bodies.

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(Corrigendum to IEEE Std 11073-20601-2014)

Health informatics—Personal health device communication

# Part 20601: Application profile— Optimized Exchange Protocol Corrigendum 1

Sponsor

IEEE 11073<sup>™</sup> Standards Committee of the IEEE Engineering in Medicine and Biology Society

Approved 3 September 2015

**IEEE-SA Standards Board** 

**Abstract:** Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard defines a common framework for making an abstract model of personal health data available in transport-independent transfer syntax required to establish logical connections between systems and to provide presentation capabilities and services needed to perform communication tasks. The protocol is optimized to personal health usage requirements and leverages commonly used methods and tools wherever possible.

This corrigendum removes the ambiguities and corrects the wrong nomenclature codes and qualifier status that have been identified in IEEE Std 11073-20601-2014 to improve implementation of the standard in an interoperable fashion.

**Keywords:** IEEE 11073<sup>™</sup>, IEEE 11073-20601<sup>™</sup>, medical device communication, personal health devices

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#### Introduction

This introduction is not part of IEEE Std 11073-20601<sup>TM</sup>-2014/Cor 1-2015, Health informatics—Personal health device communication—Part 20601: Application profile—Optimized Exchange Protocol—Corrigendum 1.

ISO and IEEE 11073 standards enable communication between medical devices and external computer systems. This standard and corresponding IEEE 11073-104xx standards address a need for a simplified and optimized communication approach for personal health devices, which may or may not be regulated devices. These standards align with, and draw upon, the existing clinically focused standards to provide easy management of data from either a clinical or personal health device.

This document addresses a need for an openly defined, independent standard for converting the collected information into an interoperable transmission format so the information can be exchanged between agents and managers.

This standard removes the ambiguities and corrects the wrong nomenclature codes and qualifier status that have been identified in IEEE Std 11073-20601-2014 to improve implementation of the standard in an interoperable fashion.

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#### Health informatics—Personal health device communication

# Part 20601: Application profile— Optimized Exchange Protocol

### **Corrigendum 1**

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NOTE—The editing instructions contained in this corrigendum define how to merge the material contained therein into the existing base standard and its amendments to form the comprehensive standard.

The editing instructions are shown in **bold italic**. Four editing instructions are used: change, delete, insert, and replace. **Change** is used to make corrections in existing text or tables. The editing instruction specifies the location of the change and describes what is being changed by using strikethrough (to remove old material) and <u>underscore</u> (to add new material). **Delete** removes existing material. **Insert** adds new material without disturbing the existing material. Insertions may require renumbering. If so, renumbering instructions are given in the editing instruction. **Replace** is used to make changes in figures or equations by removing the existing figure or equation and replacing it with a new one. Editing instructions, change markings, and this NOTE will not be carried over into future editions because the changes will be incorporated into the base standard.

#### 6. Personal health device DIM

#### 6.3 Personal health object class definitions

Change Source-Handle-Reference and Source-Handle-Reference-List rows in Table 6 as shown:

**Table 6—Metric Attributes** 

Attribute	Attribute ID	Attribute	Remark	Qualifiers
name		type		
Source-	MDC_ATTR_SOURCE_	HANDLE	This attribute establishes a relation of this	Optional
Handle-	HANDLE_REF		object instance to a source object (e.g., pulse	Dynamic
Reference			references sourcing SpO2). This attribute is	
			used whenever it is required to model an	
			explicit relation between object instances to	
			define dependencies. The usage of this	
			attribute is defined by device specializations.	
			A metric object may contain one of Source-	
			Handle-Reference or Source-Handle-	
			Reference-List, but not both.	
			If a measurement reports a Source-Handle-	
			Reference or Source-Handle-Reference-List	
			attribute, the measurement from the object(s)	
			that it references shall be sent by the agent to	
			the manager must have been sent prior to the	
			sending of this measurement.	
Source-	MDC_ATTR_SOURCE_	HANDLE	This attribute establishes a relation of this	Optional
Handle-	HANDLE_REF_LIST	List	object instance to more than one source	Dynamic
Reference-			objects (e.g., body mass index (BMI)	
List			references sourcing Height and Weight). This	
			attribute is used whenever it is required to	
			model an explicit relation between object	
			instances to define dependencies. The usage of	
			this attribute is defined by device	
			specializations. A metric object may contain	
			one of Source-Handle-Reference or Source-	
			Handle-Reference-List, but not both.	
			If a measurement reports a Source-Handle-	
			Reference or Source-Handle-Reference-List	
			attribute, the measurement from the object(s)	
			that it references shall be sent by the agent to	
			the manager must have been sent prior to the	
			sending of this measurement.	

#### 6.3.7 PM-store class

#### 6.3.7.3 PM-store class attributes

Delete the following text:

The attributes Handle and PM-Store-Capab are part of the agent configuration; therefore, the manager knows the corresponding attribute values after the Configuring procedure.

#### 6.3.7.4 PM-store object methods

Change the first paragraph after Table 11 as shown:

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If an agent supports the PM-store class, the support of the Get-Segment-Info or Get Segment Id List methods is mandatory, and support of the Trig-Segment-Data-Xfer method is mandatory. Support for the Clear-Segments and Get-Segment-Id-List method is optional and is indicated in the PM-Store-Capab attribute.

#### Delete text in Get-Segment-Info as shown:

#### — Get-Segment-Info:

This method allows the manager to retrieve PM-segment attributes of one or more PM-segments, with the exception of the Fixed-Segment-Data attribute, which contains the actual stored data and is retrieved by using the Trig-Segment-Data-Xfer method. In particular, the Get-Segment-Info method allows the manager to retrieve the attributes and their data contents from the PM-segment object instances identified by the SegmSelection parameter.

The agent shall support the all-segments choice in the SegmSelection action-info-args of the Get-Segment-Info method. The agent may support the segm-id-list and/or abs-time-range and/or bo-time-range choice in the SegmSelection action-info-args of the Get-Segment-Info method. In this case the agent shall set the pmsc-segm-id-list-select and/or pmsc-abs-time-select flag in the PM-Store-Capab attribute. If the manager sends the Get-Segment-Info method with the choice that the agent does not support, the agent shall reply with an unsupported-choice error (roer).

For PM-segment info returned by time, the segments are selected using the same mechanism as described under Clear-Segments.

If the manager supports sending the Get-Segment-Info method, the manager shall support at least the choice all-segments in the SegmSelection action-info-args of the Get-Segment-Info method. The manager may support additional choices.

If a standard configuration contains any PM-Store object, the manager must send Get-Segment-info or Get-Segment-Id-List at the beginning of accessing any PM-Store object.

If no PM-Segment matches the selection criteria in the SegmSelection action-info-args so that no PM-segments are found by the action, then this is not an error, a normal response is sent, and the segment info list will just be empty.

If the choice of SegmSelection in the Get-Segment-Info method is segm-id-list and the segm-id-list is empty, then the response shall be a segment-info-list that is empty.

If the agent supports the Get Segment Info method, the agent shall set the pmsc get segm info sup flag in the PM-Store-Capab attribute.

#### Insert text in Get-Segment-Id-List as shown:

#### Get-Segment-Id-List

This method allows the manager to retrieve a list of the instance numbers of all the PM-segments of a PM-store. In particular, the Get-Segm-Id-List method allows the manager to then retrieve the attributes of selected PM-segment object instances and their data contents without needing to retrieve information of all PM-segments. This also allows the manager to retrieve multiple PM-segments as a series of requests.

If a standard configuration contains any PM-Store object, the manager must send Get-Segment-Info or Get-Segment-Id-List at the beginning of accessing any PM-Store object.

If the agent supports the Get-Segment-Id-List method, the agent shall set the pmsc-get-segm-id-list-sup flag in the PM-Store-Capab attribute.

If the agent supports the Get-Segment-Id-List method, the agent shall also support the Get-Segment-Info method with the segm-id-list choice in the SegmSelection action-info-args.

#### 7. Personal health device service model

#### 7.4 Specific application of object access EVENT REPORT services for personal health devices

#### 7.4.3 Configuration event report

#### 7.4.3.2 Agent device configuration

Change the second paragraph as shown:

The MDS object is not considered part of the configuration. A manager reassociating with an agent offering the same Dev-Configuration-Id cannot expect the MDS attribute values to be the same; for example, an agent may clear the mds-time-mgr-set-timemanager-set-time bit as its clock has already been set.

#### 8. Communication model

#### 8.7 Associating procedure

- 8.7.3 Normal procedures
- 8.7.3.1 Agent procedure
- 8.7.3.1.2 Data exchange protocol –defined by this standard

Change the first dash-list item as shown:

— The protocol-version field contains the versions of the data exchange protocol the agent can support.

#### 8.9 Operating procedure

- 8.9.3 Normal procedures
- 8.9.3.3 Measurement data transfer
- 8.9.3.3.7 Scan report number management

Change the last paragraph as shown:

An agent-initiated transfer from the MDS or scanner objects, by way of contrast, establishes a flow that terminates only when the association is broken. Thus for the agent-initiated transfer, the scan-report-no starts at 0, but cannot be reset by the manager within the context of the association. Setting the scanner's Operational-State attribute to disabled halts transmission of event reports, i.e., internal observation of metric objects is halted and continues again after setting the Operational-State attribute to enabled again. The scan-report-no in this case will continue counting from where it was halted. Note that there will be a separate scan-report-no for confirmed (data-req-id 0xF000) and unconfirmed (data-req-id 0xF001) scan event reports.

#### 8.9.3.4 Persistently stored metric data transfer

#### 8.9.3.4.2 Persistently stored metric data transmission

Change the last paragraph in item b) as shown:

b) **Retrieving the PM-segment information.** The manager retrieves information on the segments in a PM-store by sending an ACTION.Get-Segment-Info or ACTION.Get-Segment-Id-List command to the specific PM-store (see Figure 21 and Figure 22) with a request to return information from all segments, a particular list of segments, or any segments within a given time range. If there is no segment in any of these three cases, the agent responds with an empty list. The agent shall support the first selection criteria and may provide support for the second and third selection criteria. The manager is able to determine whether the agent provides support by inspecting pmsc-abs-time-select in the PM-Store-Capab attribute of the PM-store information retrieved earlier.

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The agent responds to the ACTION.Get-Segment-Info command with a list of segment numbers followed by the full attribute list for each of the segments. The agent responds to the ACTION. Get-Segment-Id-List command with a list of the instance numbers.

If the manager invokes one of the optional Get-Segment-Info or Get-Segment-Id-List methods but the agent does not support the particular optional action (list of segments or range of segments by time), then the agent shall respond with a roer DataApdu with an RoerErrorValue of "not-allowed-by-object".

#### Annex A

(normative)

#### ASN.1 definitions

#### A.4 ACTION-method-related data types

Insert the following new lines:

- -- SegmIdList selects PM-segments by ID.
- -- SegmIdList may be returned in response to the Get-Segment-Id-List method, containing a list of
- -- the instance numbers of all the PM-segments of a PM-store.

SegmIdList ::= SEQUENCE OF InstNumber

#### Change the text as shown:

- -- SegmentInfoList returns the object attributes (except the Fixed-Segment-Data) of all
- -- selected PM-segment object instances in response to the Get-Segment-Info or Get Segment Id List
- -- PM-store method.
- -- This is required by the manager to retrieve the dynamic information about the segments.

SegmentInfoList ::= SEQUENCE OF SegmentInfo

#### A.11 Data types for new object attributes and object services

#### A.11.8 PM-store and PM-segment related data types

Delete the line containing "pmsc-get-segm-info-sup" as shown:

-- instance. The default value of this attribute is 0 (no bits set).

- -- The PM-Store-Capab attribute defines specific static capabilities and properties of the PM-store object
- -- All unassigned " PmStoreCapab " bit values are reserved for future expansion and shall be set to zero.

PmStoreCapab ::=BITS-16 {

pmsc-var-no-of-segm(0), -- indicates that the number of PM-segments -- contained in this PM-store is dynamic and may

-- change

-- PM-segments in the SegmSelection data type can pmsc-segm-id-list-select(3),

-- be selected by defining a list of segment IDs

pmsc-epi-seg-entries(4), -- some/all PM-segments contain

> -- episodic/aperiodic entries and therefore have -- to contain explicit time stamp information

pmsc-peri-seg-entries(5), -- some/all PM-segments contain periodically

-- sampled entries and therefore the PM-segment

-- or PM-store shall support the

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	Sample-Period attribute
pmsc-abs-time-select(6),	PM-segments in the SegmSelection data type can
	be selected by defining an abs-time-range or
	bo-time-range depending upon which time
	mode the device supports
pmsc-clear-segm-by-list-sup(7),	clearing a list of segments is supported
pmsc-clear-segm-by-time-sup(8),	clearing segments by abs-time-range or
	bo-time-range is supported depending
	upon which time mode the device supports
pmsc-clear-segm-remove(9),	if this bit is set, the agent will completely remove
	the specified PM-segment instance as part of the
	Clear-Segment method. If this bit is not set, it will
	just remove all entries from the specified
	PM-segment.
pmsc-clear-segm-all-sup(10),	clearing all segments is supported
pmsc-multi-person(12)	The PM-store supports PM-segment for more
	than one person
pmsc get segm info sup(13),	The Get Segment Info method is supported.
pmsc-get-segm-id-list-sup(14),	The Get-Segment-Id-List method is supported.

}

#### Annex I

(normative)

#### **Nomenclature codes**

Insert the following row of code into the MDC_PA#define MDC_ATTR_SEG_FIXED_DATA 2641 /*	$RT\_OBJ$ partition after the row that begins with			
#define MDC ATTR PM SEG ELEM STAT ATTR	R 2642 /* */			
Insert the following row of code into the MDC_PA#define MDC_ATTR_SCAN_HANDLE_LIST 2679				
#define MDC ATTR SOURCE HANDLE REF LIS	T 2681 /* */			
Delete one row under the MDC_PART_INFRA partition as shown:				
#define MDC_DEV_SPEC_PROFILE_RESP_RATE	4114 /* Respiration rate */			
Change five rows of code under the MDC_PART_INFRA partition as shown:				
#define MDC_DEV_SPEC_PROFILE_COAG #define MDC_DEV_SPEC_PROFILE_URINE_ANAI #define MDC_DEV_SPEC_PROFILE_SLEEP_QUAI #define MDC_DEV_SPEC_PROFILE_SABTESLEEP #define MDC_DEV_SPEC_PROFILE_CGM	LYZER 41198 /* Urine analyzer */ LITY 411920 /* Sleep quality monitor */ PAPONEA 41240 /* Sleep apenoea breathing therapy deviceequipment */			
Insert the following two rows of code into the MDC_PART_INFRA partition after the row that begins with:				
#define MDC_TIME_SYNC_OTHER	7948 /*A time sync method that is out of the scope of IEEE Std 11073-20601*/			
#define MDC TIME SYNC OTHER MOBILE	7949 /*A time sync method based on other mobile network technology which is not listed			
#define MDC TIME SYNC GPS	above */ 7950 /*A time sync method based on GPS information */			