BS EN ISO 11073-10418:2014
Incorporating corrigendum June 2014

BSI Standards Publication

Health informatics — Personal health device communication

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

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The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

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Published by BSI Standards Limited 2014

ISBN 978 0 580 86985 3

ICS 35.240.80

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This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 March 2014.

Amendments/corrigenda issued since publication

Date	Text affected
30 June 2014	CEN correction notice 21 May 2014 implements ISO/IEEE corrected text 01 May 2014, which removes IEEE licensing text from footers

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 11073-10418

March 2014

ICS 35.240.80

English Version

Health informatics - Personal health device communication - Part 10418: Device specialization - International Normalized Ratio (INR) monitor (ISO/IEEE 11073-10418:2014, Corrected version 2014-05-01)

Informatique de santé - Communication entre dispositifs médicaux sur le site des soins - Partie 10418: Spécialisation des dispositifs - Surveillance du rapport normalisé international (INR) (ISO/IEEE 11073-10418:2014, Version corrigée 2014-05-01)

Medizinische Informatik - Kommunikation von Geräten für die persönliche Gesundheit - Teil 10418: Gerätespezifikation - Monitor für den international standardisierter Thromboplastinzeit-Quotient (INR) (ISO/IEEE 11073-10418:2014, korrigierte Fassung 2014-05-01)

This European Standard was approved by CEN on 14 December 2013.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Foreword

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Foreword

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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 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*

— *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*

— *Part 10471: Device specialization — Independant 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*

— *Part 30200: (Point-of-care medical device communication) Transport profile — Cable connected*

— *Part 30300: (Point-of-care medical device communication) Transport profile — Infrared wireless*

— *Part 30400: (Point-of-care medical device communication) Interface profile — Cabled Ethernet*

— *Part 90101: (Point-of-care medical device communication) Analytical instruments — Point-of-care test*

— *Part 91064: (Standard communication protocol) Computer-assisted electrocardiography*

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Health informatics—Personal health device communication

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

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IEEE
3 Park Avenue
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IEEE Std 11073-10418™-2011

9 November 2011

Health informatics—Personal health device communication

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

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Approved 10 September 2011

IEEE-SA Standards Board

Abstract: A normative definition of communication between personal telehealth International Normalized Ratio (INR) devices (agents) 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. Work done in other ISO/IEEE 11073 standards is leveraged, including existing terminology, information profiles, 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 functionality of INR devices is defined in this standard. In the context of personal health devices, the measurement of the prothrombin time (PT) that is used to assess the level of anticoagulant therapy and its presentation as the International Normalized Ratio compared to the prothrombin time of normal blood plasma is referred to in INR monitoring. Applications of the INR monitor include the management of the therapeutic level of anticoagulant used in the treatment of a variety of conditions. The data modeling and its transport shim layer according to ISO/IEEE 11073-20601:2010 are provided by this standard, and the measurement method is not specified.

Keywords: IEEE 11073-10418, International Normalized Ratio (INR) monitor, medical device communication, personal health devices

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3 Park Avenue, New York, NY 10016-5997, USA

PDF: ISBN 978-0-7381-6704-6 STD97137
Print: ISBN 978-0-7381-6705-3 STDPD97137

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Introduction

This introduction is not part of IEEE Std 11073-10418-2011, Health informatics—Personal health device communication—Part 10418: Device specialization—International Normalized Ratio (INR) monitor.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of the communication between medication 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 ambiguity in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for personal telehealth INR devices. In this context, the measurement of the prothrombin time (PT) that is used to assess the level of anticoagulant therapy and its presentation as the International Normalized Ratio (INR) compared with the PT of normal blood plasma is referred to in INR monitoring. Applications of the INR monitor include the management of the therapeutic level of anticoagulant used in the treatment of a variety of conditions.

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Health informatics—Personal health device communication

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

1. Overview

1.1 Scope

The scope of this standard is to establish a normative definition of communication between personal telehealth International Normalized Ratio (INR) 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 INR devices.

In the context of personal health devices, INR monitoring refers to the measurement of the prothrombin time (PT) that is used to assess the level of anticoagulant therapy and its presentation as the International Normalized Ratio compared to the prothrombin time of normal blood plasma. Applications of the INR monitor include the management of the therapeutic level of anticoagulant used in the treatment of a variety of conditions.

This standard provides the data modeling and its transport shim layer according to IEEE Std 11073-20601a™-2010[1] and does not specify the measurement method.

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

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, and set top boxes). Interoperability is 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 for an overview of the environment within which this standard is written.

This standard defines the device specialization for the INR 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, which in turn draws information from both ISO/IEEE 11073-10201:2004 [B9][2] and ISO/IEEE 11073-20101:2004 [B10]. The medical device encoding rules (MDERs) used within this standard are fully described in IEEE Std 11073-20601a-2010.

This standard reproduces relevant portions of the nomenclature found in ISO/IEEE 11073-10101:2004 [B8] and adds new nomenclature codes for the purposes of this standard. Between this standard 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. It contains new material and corrections and does not copy the content of ISO/IEEE 11073-20601:2010. 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.[3]

NOTE 2—In this standard, ISO/IEEE 11073-104zz 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, Health informatics—Personal health device communication—Application profile—Optimized Exchange Protocol.[6]

See Annex A for all informative material referenced by this standard.

[2] The numbers in brackets correspond to those of the bibliography in Annex A.
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3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this document, the following terms and definitions apply. *The IEEE Standards Dictionary: Glossary of Terms & Definitions* should be 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, it describes the attributes, methods, and events that objects instantiated from the class utilize.

compute engine: *See:* **manager.**

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.

International Standardized Ratio (INR): The globally recommended normalized unit for measuring prothrombin time.

International Sensitivity Index (ISI): Standardized calibration for a thromboplastin compared to the World Health Organization (WHO) standard.

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 computer system.

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.**

prothrombin time (PT): The time taken for a clot to form on the addition of a thromboplastin to a sample of venous or capillary blood that is measured in seconds.

3.2 Acronyms and abbreviations

APDU	application protocol data unit
ASN.1	Abstract Syntax Notation One
DIM	domain information model
EUI-64	extended unique identifier (64 bits)
ICS	implementation conformance statements
INR	International Normalized Ratio
ISI	International Sensitivity Index
MDC	medical device communication
MDER	medical device encoding rule
MDS	medical device system
MOC	managed object class
OID	object identifier
PDU	protocol data unit
PHD	personal health device

[7] *The IEEE Standards Dictionary: Glossary of Terms & Definitions* is available at http://shop.ieee.org/.

PT	prothrombin time
VMO	virtual medical object
VMS	virtual medical system
WHO	World Health Organization

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 11073-20601a-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. This standard defines aspects of the INR monitor device. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 PHD INR 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). 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 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 standard and its parts, such as IEC 60601-1-1:2000 [B2], with respect to electrical and mechanical safety, and any device-specific standard as might be defined in IEC 60601-1-2:2007 [B3]. Software aspects may apply through standards such as IEC 62304:2006/ EN 62304:2006 [B5].

Devices that comply with this standard shall 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. Additionally, the network environment within which devices operate should be specified. Use of any medical equipment within a network environment shall be subject to risk assessment and risk management appropriate to the application and use and should adhere to standards such as ISO 14971:2007 [B7] and IEC 80001-1:2010 [B6]. The requirements of such risk assessment and risk management and conformance are outside the scope of this standard.

5. INR monitor device concepts and modalities

5.1 General

This clause presents the general concepts of INR monitor devices. In the context of personal health devices in this family of standards, an INR monitor is a device that determines the normalized ratio for the coagulation time when a thromboplastin reagent is added to a sample of venous or capillary blood. In general, the INR monitor will be taking a measurement that is representative of the coagulation time of the blood, and it is used to follow the status of anticoagulation therapy in patients using an oral anti-vitamin K anticoagulant, such as warfarin.

Typically, such measurements are initially needed frequently and, depending on the patient, the adjustment of dose of medication requires some time. Travelling to the healthcare professional or laboratory means time off for active people, less independence, and a disruption of daily routine. Later, when the patient is properly adjusted and stabilized, INR monitoring is commonly done at intervals of 3 to 4 weeks.

Coagulation tests are performed on the plasma fraction of blood. In the laboratory, this is usually on plasma separated from citrated blood by centrifugation, but where testing can be performed immediately, in point-of-care test devices, often on the plasma fraction of a native (noncitrated) sample of whole blood. The liquid serum that is left following the formation of a blood clot is not useful for blood coagulation testing.

INR meters are usually small, portable devices that are carried around by the user so that measurements may be taken as needed, whether or not the user is in a network environment where communications with a hosting device can be established. Hence, measurement data are typically logged within the meter and can be retrieved at a later time, either in whole or in part, when the meter is connected to a hosting device network. There are two typical use cases for the transfer of measurement data to a hosting device:

— By the user in a non–health-care environment. A user may connect the meter to a personal hosting device such as a personal computer or a portable communications device such as a cell phone. In this case, the user would download the most recent logged measurement data from the meter for near-term trend analysis, or for transfer of data to an external electronic health network service. Transfer of data would happen immediately on connection with the hosting application and require no initiation by the user. This is a temporary storage model of the meter.

— By a health-care professional in an office or clinic environment. The health-care professional would download all logged measurement data from the meter for longer term analysis, such as the data logged since the patient's last appointment. Transfer of data would be controlled entirely by the hosting application and would not necessarily happen automatically when a connection is established. This is a long-term storage model of the meter.

This standard supports configurations that allow for support of both temporary and long-term storage models.

5.2 Prothrombin time

Either venous or capillary blood can be used to monitor anticoagulation therapy. To produce a reading, thromboplastin is added to the blood to activate coagulation. This causes a blood clot to form. The time it takes for this clot to form is measured in seconds and is known as the prothrombin time.

5.3 Quick value

In some European countries, blood coagulability was typically expressed in a unit known as the Quick value. In this case, the measured prothrombin time is expressed in relation to the coagulation time of a healthy person. The value obtained is the "percentage of the standard value." In a person not receiving oral anticoagulation, the "normal" Quick value is between 80% and 120%. A Quick value of only 30%, for instance, indicates that the blood coagulation time is longer than normal. The longer the patient's coagulation time, the lower the Quick value.

5.4 International Sensitivity Index (ISI)

Prothrombin time is the primary test for monitoring anti-vitamin K oral anticoagulants such as warfarin, but it is influenced by preanalytical conditions and analytical variables, including the thromboplastin reagents and instrumentation used. To standardize the test results, the PT results are transformed into INR by calibration of the reagent/instrument system with International Reference standards according to World Health Organization (WHO) guidelines.

Every manufacturer of thromboplastin must calibrate it against the WHO standard (two references exist: one for human recombinant-based thromboplastins and one for rabbit-brain-based ones). The value obtained is known as the ISI. This enables the various sensitivities of the thromboplastins to be ascertained.

5.5 International Normalized Ratio

In patients stabilized on anti-vitamin K anticoagulants, the INR makes coagulation measurements extensively comparable despite the numbers of different thromboplastins used.

$$INR = (\text{Patient's PT} / \text{Normal mean PT})^{ISI}$$

For example: The PT of a patient receiving oral anticoagulant is 64 s. The prothrombin time of a normal plasma is 22 s. The ISI of the thromboplastin used is 0.93. Substituting this value in the preceding formula produces the following INR:

$$(64 / 22)^{0.93} = 2.7 \text{ INR}$$

This signifies a coagulation time that is approximately 2.7 times longer than the mean prothrombin time in a healthy non-anticoagulated individual; the longer the patient's coagulation time, the higher the INR. The unit is specified as INR.

5.6 Control calibration

INR monitors are tested periodically for correct measurement by using a specially prepared strip to check the calibration of the monitor.

5.7 Batch/code number

This shall record information from a strip such as the batch number or similar information.

5.8 Device and sensor status

This provides specific information on the device or a sensor that can assist in determining the source of a problem in usage or due to a fault. Specifically, it will indicate when a measurement is invalid due to a problem in the measurement test strip or reagent.

5.9 Device alarm conditions

This provides information on any device-specific alarm conditions.

5.10 INR value out of bounds

This device provides an alarm whenever an INR value exceeds the thresholds for INR; the alarm occurs when the value is too high (danger of hemorrhage) or too low (danger of clotting). This standard currently does not support alarms for INR value out of bounds.

5.11 Extended capabilities

The INR monitor may, in addition to its measuring capabilities, have the capabilities to provide extended functionality as in the subsequent sections.

5.12 Target level for INR

This provides the current target level of INR set for the patient. This value is used to determine alarm conditions and in algorithms to determine the recommended new level of medication.

5.13 Current level of medication

This allows the patient to record into the device the current level of their anticoagulation medication so that a physician may assess the success of the therapeutic level. This is normally to be reported as the average level of medication in milligrams. Typically, patients may take varying levels of medication on separate days to achieve the correct therapeutic dose.

5.14 Recommended new level of medication

Devices capable of applying an algorithm to advise a patient on a new average level of medication can record the recommended new level of medication. The new level will be based on an associated INR measurement and current level of medication, and these shall have the same time stamp.

Information on the algorithm may be provided by the manufacturer as a reference.

5.15 Context information

In addition to INR measurement, an INR meter may provide a means for the user to associate additional information on the context in which or by whom the measurement was made.

6. International Normalized Ratio monitor domain information model

6.1 Overview

This clause describes the domain information model of the INR 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 INR monitor domain information model, defined for the purposes of this standard, is shown in Figure 1.

The objects of the DIM, as shown in Figure 1, are described in 6.5 through 6.10. This includes the medical device system (MDS) object (6.5), the numeric objects (6.6), the RT-SA objects (6.7), the enumeration objects (6.8), the PM-store objects (6.9), and the scanner objects (6.10). Subclause 6.11 specifies the rules for extending the INR monitor information model beyond elements as described in this standard. Each subclause that describes an object of the INR monitor contains the following information:

— The nomenclature code used to identify the class of the object. One example where this code is used is the configuration event, where the object class is reported for each object. This allows the manager to determine whether the class of the object being specified is a numeric, real-time sample array, enumeration, scanner, or PM-store class.

— The attributes of the object. Each object has attributes that represent and convey information on the physical device and its data sources. Each object has a Handle attribute that identifies the object instance within an agent. Attribute values are accessed and modified using methods such

as GET and SET. Attribute types are defined using ASN.1. The ASN.1 definitions for new attribute types specific to this standard are in Annex B, and the ASN.1 definitions for existing attribute types referenced in this standard are in IEEE Std 11073-20601a-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. 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.

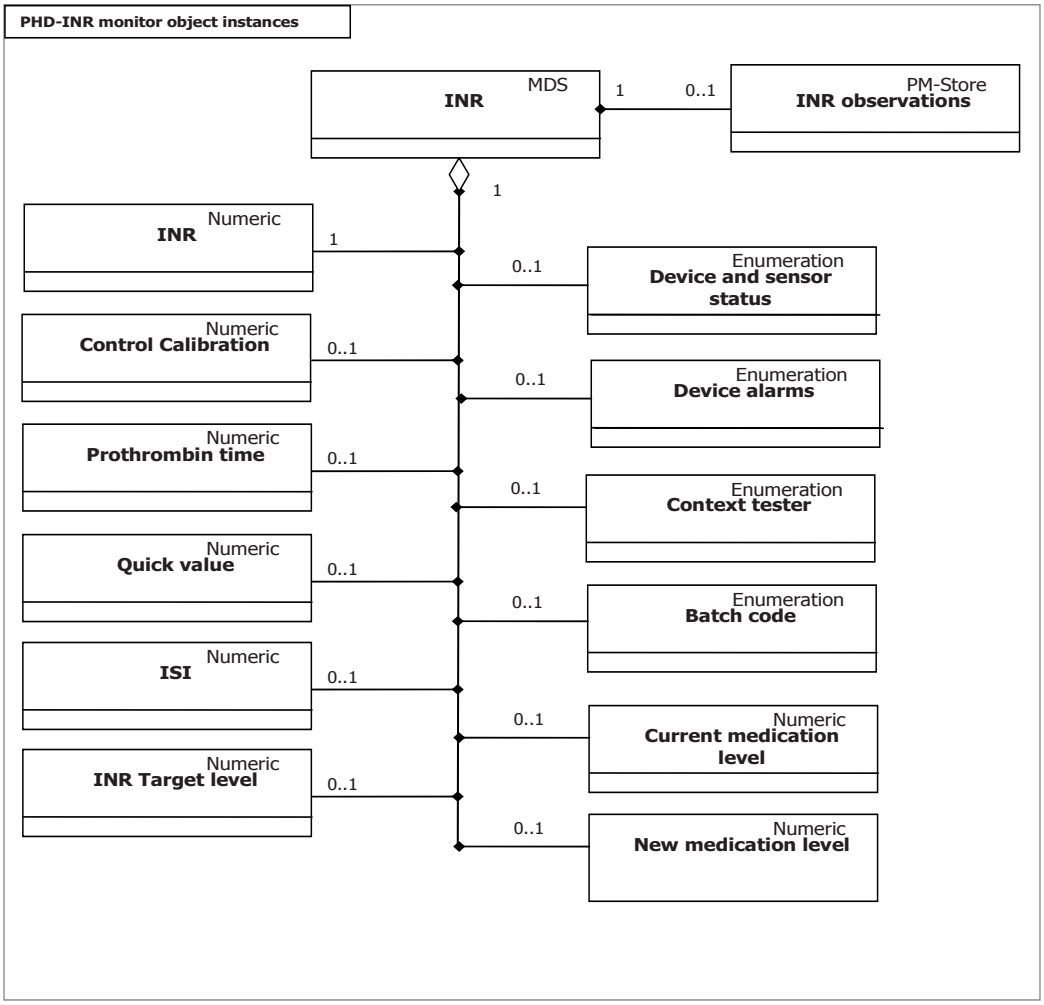

Figure 1—INR monitor—domain information model

6.4 Types of configuration

6.4.1 General

As specified in IEEE Std 11073-20601a-2010, there are two styles of configuration available. Subclauses 6.4.2 and 6.4.3 briefly introduce standard and extended configurations.

6.4.2 Standard configuration

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

Two standard configurations are defined in this standard. Standard configuration 1800 (0x0708) contains only an INR numeric object as defined in 6.6.2. Standard configuration 1801 (0x0709) contains an INR numeric object and a control solution numeric object as defined in 6.6.3.

6.4.3 Extended configuration

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

6.5 Medical device system object

6.5.1 MDS object attributes

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

Table 1—MDS object attributes

Attribute name	Value	Qual.
Handle	0	M
System-Type	Attribute not present. See IEEE Std 11073-20601a-2010.	C
System-Type-Spec-List	{MDC_DEV_SPEC_PROFILE_COAG, 1}.	M
System-Model	{“Manufacturer”,”Model”}.	M
System-Id	Extended unique identifier (64-bits) (EUI-64) See IEEE Std 11073-20601a-2010.	M
Dev-Configuration-Id	Standard config: 0x0708 (1800) 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
Base-Offset-Time	See IEEE Std 11073-20601a-2010.	R
Relative-Time	See IEEE Std 11073-20601a-2010.	C
HiRes-Relative-Time	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
Confirm-Timeout	See IEEE Std 11073-20601a-2010.	O

NOTE—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

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

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

The Dev-Configuration-Id attribute holds a locally unique 16-bit identifier that identifies the device configuration. For an INR monitor agent with extended configuration, 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.

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

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

6.5.2 MDS object methods

Table 2 defines the methods (actions) of the MDS object. These methods are invoked using the Action service. In Table 2, the Subservice type name column defines the name of the method; the Mode column defines whether the method is invoked as an unconfirmed action (i.e., roiv-cmip-action from IEEE Std 11073-20601a-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 for ASN.1 definitions) to use in the

action message for the action-info-args field of the request; and the Results (action-info-args) column defines the structure to use in the action-info-args of the response.

Table 2—MDS object methods

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

Set-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, this method shall be implemented.

Agents following only this device specialization and no others shall send event reports using agent-initiated measurement data transmission. Agents following this device specialization as well as others shall send event reports in the appropriate fashion. During the association procedure (see 8.3), data-req-mode-capab shall be set to the appropriate value for the event report style. As a result, the manager shall assume the INR monitor agent does not support any of the MDS-Data-Request features (see IEEE Std 11073-20601a-2010 for additional information). Thus, implementation of the MDS-Data-Request method/action is not required in this standard and is not shown in Table 2.

6.5.3 MDS object events

Table 3 defines the events that can be sent by the INR monitor MDS object.

Table 3—INR monitor 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	Config Report Rsp
	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 INR monitor agent during the configuring procedure if the manager does not already know the INR monitor agent's configuration from past associations or because the manager has not been implemented to recognize the configuration according to the INR monitor device specialization. The event provides static information about the supported measurement capabilities of the INR monitor agent.

MDS-Dynamic-Data-Update-Var:
This event provides dynamic measurement data from the INR monitor agent numeric and enumeration object(s). These data are reported using a generic attribute list variable format. The event is sent as an unsolicited message by the agent (i.e., an agent-initiated measurement data transmission). See 8.5.3 for more information on unsolicited event reporting.

MDS-Dynamic-Data-Update-Fixed:
This event provides dynamic measurement data from the INR monitor agent numeric and enumeration object(s). These data are reported in the fixed format defined by the Attribute-Value-Map attribute of the object. The event is sent as an unsolicited message by the agent (i.e., an agent-initiated measurement data transmission). See 8.5.3 for more information on unsolicited event reporting.

MDS-Dynamic-Data-Update-MP-Var:
This is the same as MDS-Dynamic-Data-Update-Var but allows inclusion of data from multiple people.

MDS-Dynamic-Data-Update-MP-Fixed:
This is the same as MDS-Dynamic-Data-Update-Fixed but allows inclusion of data from multiple people.

NOTE—IEEE Std 11073-20601a-2010 requires that managers support all of the MDS object events listed previously.

6.5.4 Other MDS services

6.5.4.1 GET service

An INR monitor agent shall support the GET service, which is provided by the MDS object to retrieve the values of all implemented MDS object attributes. The GET service can be invoked as soon as the INR monitor agent receives the Association Response and moves to the Associated state, including the Operating and Configuring substates.

The manager may request the MDS object attributes of the INR monitor agent; in which case, the manager shall send the "Remote Operation Invoke | Get" message (see roiv-cmip-get in IEEE Std 11073-20601a-2010) with the reserved MDS handle value of 0. The INR monitor agent shall report its MDS object attributes to the manager using the "Remote Operation Response | Get" message (see rors-cmip-get in IEEE Std 11073-20601a-2010). See Table 4 for a summary of the GET service including some message fields.

Table 4—INR monitor MDS object GET service

Service	Subservice type name	Mode	Subservice type	Parameters	Results
GET	<na>	<implied confirmed>	<na>	GetArgumentSimple = (obj-handle = 0), attribute-id-list *<optional>*	GetResultSimple = (obj-handle = 0), attribute-list

See 8.5.2 for details on the procedure for getting the MDS object attributes.

6.5.4.2 SET service

The INR monitor specialization does not require an implementation to support the MDS object SET service.

6.6 Numeric objects

6.6.1 General

The INR monitor DIM (see Figure 1) contains numeric objects that represent aspects of blood coagulation and associated medical events. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. Table 5 shows the attributes that are common to all the numeric types of the INR monitor agent.

Table 5—Common numeric object attributes

Attribute name	Extended configuration		Standard configurations (Dev-Configuration-Id = 0x0708) (Dev-Configuration-Id = 0x0709)	
	Value	Qual.	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M	Defined in each respective table.	M
Type	Defined in each respective table.	M	Defined in each respective table.	M
Supplemental-Types	See IEEE Std 11073-20601a-2010.	NR	See IEEE Std 11073-20601a-2010.	NR
Metric-Spec-Small	mss-avail-intermittent, mss-avail-stored-data, mss-upd-aperiodic, mss-msmt-aperiodic, mss-acc-agent-initiated unless otherwise defined in a respective table.	M	mss-avail-intermittent, mss-avail-stored-data, mss-upd-aperiodic, mss-msmt-aperiodic, mss-acc-agent-initiated unless otherwise defined in a respective table.	M
Metric-Structure-Small	See IEEE Std 11073-20601a-2010.	NR	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010.	NR
Measurement-Status	See IEEE Std 11073-20601a-2010.	NR	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010.	NR
Metric-Id	See IEEE Std 11073-20601a-2010.	NR	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010.	NR
Metric-Id-List	See IEEE Std 11073-20601a-2010.	NR	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010.	NR
Metric-Id-Partition	See IEEE Std 11073-20601a-2010.	NR	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010.	NR
Unit-Code	Defined in each respective table.	M	Defined in each respective table.	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C	Defined in each respective table.	M
Source-Handle-Reference	See IEEE Std 11073-20601a-2010.	NR	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010.	NR
Label-String	See IEEE Std 11073-20601a-2010.	O	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010.	O
Unit-LabelString	See IEEE Std 11073-20601a-2010.	O	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601a-2010.	C	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010.	C
Base-Offset-Time-Stamp	See IEEE Std 11073-20601a-2010.	R	If fixed format is used and the standard configuration is not adjusted, this attribute is mandatory; otherwise, the conditions from IEEE Std 11073-20601a-2010 apply.	R
Relative-Time-Stamp	See IEEE Std 11073-20601a-2010.	C	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010.	C
HiRes-Time-Stamp	See IEEE Std 11073-20601a-2010.	C	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010.	C
Measure-Active-Period	See IEEE Std 11073-20601a-2010.	NR	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010.	NR
Simple-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	C	See IEEE Std 11073-20601a-2010.	C
Compound-Simple-Nu-	See IEEE Std 11073-20601a-2010.	C	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010.	C

Attribute name	Extended configuration		Standard configurations (Dev-Configuration-Id = 0x0708) (Dev-Configuration-Id = 0x0709)	
Observed-Value				
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	R	If fixed format is used and the standard configuration is unchanged, this attribute is mandatory; otherwise, the conditions from IEEE Std 11073-20601a-2010 apply.	R
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	C	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010.	C
Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	C	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010.	C
Compound-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	C	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010.	C
Accuracy	See IEEE Std 11073-20601a-2010.	NR	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010.	NR

NOTE—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

Subclauses 6.6.2 through 6.6.9 describe the numeric objects that are defined for use in the INR monitor. Each object represents a specific aspect of blood coagulation measurement or an associated medical event, and its class is denoted by the Type attribute. The description of each numeric object defines the data or events it produces, the possible states, and where appropriate, its behavior. The respective tables define the numeric values generated by the agent in response to a change in state.

Sometimes, the interpretation of one attribute value in an object depends on other attribute values in the same object. For example, Unit-Code and Unit-LabelString provide context for the observed values. Whenever a contextual attribute changes, the agent shall report these changes to the manager using an MDS object event (see 6.5.3) prior to reporting any of the dependent values.

6.6.2 International Normalized Ratio

Table 6 summarizes the attributes of the INR numeric object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. The INR numeric object shall be supported by an INR monitor agent.

Table 6—INR numeric object attributes

Attribute name	Extended configuration		Standard configurations (Dev-Configuration-Id = 0x0708) (Dev-Configuration-Id = 0x0709)	
	Value	Qual.	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M	1	M
Type	{MDC_PART_SCADA | MDC_RATIO_INR_COAG.}	M	{MDC_PART_SCADA | MDC_RATIO_INR_COAG}.	M
Metric-Spec-Small	mss-avail-intermittent, mss-avail-stored-data, mss-upd-aperiodic, mss-msmt-aperiodic, mss-acc-agent-initiated unless otherwise defined in a respective table.	M	mss-avail-intermittent, mss-avail-stored-data, mss-upd-aperiodic, mss-msmt-aperiodic, mss-acc-agent-initiated unless otherwise defined in a respective table.	M
Unit-Code	MDC_DIM_INR.	M	MDC_DIM_INR.	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C	MDC_ATTR_NU_VAL_OBS_BASIC, then MDC_ATTR_TIME_STAMP_BO.	M
Base-Offset-Time-Stamp	See IEEE Std 11073-20601a-2010.	R	If fixed format is used and the standard configuration is not adjusted, this attribute is mandatory; otherwise, the conditions from IEEE Std 11073-20601a-2010 apply.	R
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	R	If fixed format is used and the standard configuration is not adjusted, this attribute is mandatory; otherwise, the conditions from IEEE Std 11073-20601a-2010 apply.	R

NOTE—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

For an INR monitor agent with standard configuration, the AttrValMap structure (see IEEE Std 11073-20601a-2010) of the Attribute-Value-Map attribute shall contain the attribute ID and attribute length information of the Basic-Nu-Observed-Value and Base-Offset-Time-Stamp attribute in the same order as indicated in Table 6.

The INR numeric object does not support any methods, events, or other services.

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

In standard configurations 1800 (0x0708) and 1801 (0x709), an INR measurement that is above the capabilities of the device sensor shall be indicated with an observed value of +INFINITY, and an INR measurement that is below the capabilities of the device sensor shall be indicated with an observed value of –INFINITY.

6.6.3 Control calibration

Table 7 summarizes the attributes of the control calibration numeric object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. The control calibration numeric object may be supported by an INR monitor agent. In standard configuration 1801 (0x0709), the control calibration numeric object shall be supported by an INR meter agent.

Table 7—Control calibration numeric object attributes

Attribute name	Extended configuration		Standard configuration (Dev-Configuration-Id = 0x0709)	
	Value	Qual.	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010	M	2	M
Type	{MDC_PART_SCADA | MDC_COAG_CONTROL}	M	{MDC_PART_SCADA | MDC_COAG_CONTROL}	M
Metric-Spec-Small	mss-avail-intermittent, mss-avail-stored-data, mss-upd-aperiodic, mss-msmt-aperiodic, mss-acc-agent-initiated unless otherwise defined in a respective table	M	mss-avail-intermittent, mss-avail-stored-data, mss-upd-aperiodic, mss-msmt-aperiodic, mss-acc-agent-initiated unless otherwise defined in a respective table	M
Unit-Code	MDC_DIM_INR	M	MDC_DIM_INR	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010	C	MDC_ATTR_NU_VAL_OBS_BASIC, then MDC_ATTR_TIME_STAMP_BO	M
Base-Offset-Time-Stamp	See IEEE Std 11073-20601a-2010	R	If fixed format is used and the standard configuration is not adjusted, this attribute is mandatory; otherwise, the conditions from IEEE Std 11073-20601a-2010 apply	R
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010	R	If fixed format is used and the standard configuration is not adjusted, this attribute is mandatory; otherwise, the conditions from IEEE Std 11073-20601a-2010 apply.	R

NOTE—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

The control calibration numeric object does not support any methods, events, or other services.

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

In standard configurations 1800 (0x0708) and 1801 (0x709), a control calibration measurement that is above the capabilities of the device sensor shall be indicated with an observed value of +INFINITY, and a control calibration measurement that is below the capabilities of the device sensor shall be indicated with an observed value of –INFINITY.

6.6.4 Prothrombin time

Table 8 summarizes the attributes of the PT numeric object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. The PT numeric object may be supported by an INR monitor agent. It shall not be present in the standard configuration.

Table 8—PT numeric object attributes

Attribute name	Extended configuration	
	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M
Type	{MDC_PART_SCADA | MDC_TIME_PD_COAG}.	M
Metric-Spec-Small	mss-avail-intermittent, mss-avail-stored-data, mss-msmt-aperiodic, mss-acc-agent-initiated.	M
Unit-Code	MDC_DIM_SEC.	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C
Base-Offset-Time-Stamp	See IEEE Std 11073-20601a-2010.	R
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	R

NOTE—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

The prothrombin time (PT) numeric object does not support any methods, events, or other services.

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

6.6.5 Quick value

Table 9 summarizes the attributes of the quick value numeric object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. The quick value numeric object may be supported by an INR monitor agent. It shall not be present in the standard configuration.

Table 9—Quick value numeric object attributes

Attribute name	Extended configuration	
	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M
Type	{MDC_PART_SCADA | MDC_ QUICK_VALUE _COAG}.	M
Metric-Spec-Small	mss-avail-intermittent, mss-avail-stored-data, mss-msmt-aperiodic, mss-acc-agent-initiated.	M
Unit-Code	MDC_DIM_PERCENT.	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C
Base-Offset-Time-Stamp	See IEEE Std 11073-20601a-2010.	R
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	R

NOTE—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

The quick value numeric object does not support any methods, events, or other services.

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

6.6.6 International Sensitivity Index

Table 10 summarizes the attributes of the ISI numeric object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. The ISI numeric object may be supported by an INR monitor agent. It shall not be present in the standard configuration.

Table 10—ISI numeric object attributes

Attribute name	Extended configuration	
	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M
Type	{MDC_PART_SCADA | MDC_ISI_COAG}.	M
Metric-Spec-Small	mss-avail-intermittent, mss-avail-stored-data, mss-msmt-aperiodic, mss-acc-agent-initiated.	M
Unit-Code	MDC_DIM_DIMLESS.	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C
Base-Offset-Time-Stamp	See IEEE Std 11073-20601a-2010.	R
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	R

NOTE—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

The ISI numeric object does not support any methods, events, or other services.

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

6.6.7 Target level for INR

Table 11 summarizes the attributes of the numeric object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. The target level for INR numeric object may be supported by an INR monitor agent. It shall not be present in the standard configuration. Its value is a setting. If this value is entered manually by the user, then mss-cat-manual shall be set.

Table 11—Target level for INR numeric object attributes

Attribute name	Extended configuration	
	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M
Type	{MDC_PART_PHD_DM | MDC_TARGET_LEVEL_COAG}.	M
Metric-Spec-Small	mss-avail-intermittent, mss-avail-stored-data, mss-cat-setting, mss-acc-agent-initiated mss-cat-manual to be set as appropriate.	M
Unit-Code	MDC_DIM_INR.	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C
Base-Offset-Time-Stamp	See IEEE Std 11073-20601a-2010.	R
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	R

NOTE—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

The target level for INR numeric object does not support any methods, events, or other services.

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

6.6.8 Current level of medication

Table 12 summarizes the attributes of the current level of the medication numeric object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. The current level of the medication numeric object may be supported by an INR monitor agent. It shall not be present in the standard configuration. Its value is a setting. If this value is entered manually by the user, then mss-cat-manual shall be set.

Table 12—Current level of medication numeric object attributes

Attribute name	Extended configuration	
	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010	M
Type	{MDC_PART_ PHD_DM | MDC_ MED_CURRENT_COAG}	M
Metric-Spec-Small	mss-avail-intermittent, mss-avail-stored-data, mss-cat-setting, mss-acc-agent-initiated mss-cat-manual to be set as appropriate	M
Unit-Code	MDC_DIM_MILLI_G	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010	C
Base-Offset-Time-Stamp	See IEEE Std 11073-20601a-2010	R
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010	R

NOTE—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

The current level of the medication numeric object does not support any methods, events, or other services.

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

6.6.9 Recommended new level of medication

Table 13 summarizes the attributes of the recommended new level of the medication numeric object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. The recommended new level of the medication numeric object may be supported by an INR monitor agent. It shall not be present in the standard configuration. Its value is a calculation.

Table 13—Recommended new level of medication numeric object attributes

Attribute name	Extended configuration	
	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010	M
Type	{MDC_PART_ PHD_DM | MDC_ MED_NEW_COAG}	M
Metric-Spec-Small	mss-avail-intermittent, mss-avail-stored-data, mss-cat-calculation, mss-acc-agent-initiated	M
Unit-Code	MDC_DIM_MILLI_G	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010	C
Base-Offset-Time-Stamp	See IEEE Std 11073-20601a-2010	R
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010	R

NOTE—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

The recommended new level of the medication numeric object does not support any methods, events, or other services.

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

6.7 Real-time sample array objects

Real-time sample array objects are not required by this standard.

6.8 Enumeration objects

6.8.1 General

The INR monitor uses a number of optional enumeration objects to represent information and events that are related to INR and its measurement. The nomenclature code to identify the enumeration class is MDC_MOC_VMO_METRIC_ENUM. The attribute structure shown in Table 14 is common to all enumeration types. Later clauses define the precise definitions for each sensor event type and take precedence.

Table 14—INR enumeration object common attributes

Attribute name	Extended configuration	
	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M
Type	Defined in each enumeration table below.	M
Supplemental-Types	See IEEE Std 11073-20601a-2010.	NR
Metric-Spec-Small	mss-avail-intermittent | mss-avail-stored-data | mss-upd-aperiodic | mss-msmt-aperiodic | mss-acc-agent-initiated.	M
Metric-Structure-Small	See IEEE Std 11073-20601a-2010.	NR
Measurement-Status	See IEEE Std 11073-20601a-2010.	NR
Metric-Id	See IEEE Std 11073-20601a-2010.	NR
Metric-Id-List	See IEEE Std 11073-20601a-2010.	NR
Metric-Id-Partition	See IEEE Std 11073-20601a-2010.	NR
Unit-Code	See IEEE Std 11073-20601a-2010.	NR
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C
Source-Handle-Reference	See IEEE Std 11073-20601a-2010.	NR
Label-String	See IEEE Std 11073-20601a-2010.	O
Unit-LabelString	See IEEE Std 11073-20601a-2010.	O
Absolute-Time-Stamp	See IEEE Std 11073-20601a-2010.	C
Base-Offset-Time-Stamp	See IEEE Std 11073-20601a-2010.	R
Relative-Time-Stamp	See IEEE Std 11073-20601a-2010.	C
HiRes-Time-Stamp	See IEEE Std 11073-20601a-2010.	C
Measure-Active-Period	See IEEE Std 11073-20601a-2010.	NR
Enum-Observed-Value-Simple-OID	See IEEE Std 11073-20601a-2010.	C
Enum-Observed-Value-Simple-Bit-Str	Explained in following clauses	C
Enum-Observed-Value-Basic-Bit-Str	See IEEE Std 11073-20601a-2010.	C
Enum-Observed-Value-Simple-Str	See IEEE Std 11073-20601a-2010.	C
Enum-Observed-Value	See IEEE Std 11073-20601a-2010.	C
Enum-Observed-Value-Partition	See IEEE Std 11073-20601a-2010.	C

NOTE—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

Subclauses 6.8.2 through 6.8.4 describe the possible uses of the INR enumeration object. Each use is an instance of the enumeration class with a particular Type value. The interpretation of associated values is dependent on the Type value. The description of each enumeration object defines all the possible states and, where appropriate, its behavior. The respective tables define the events generated by the agent in response to a change in state.

The enumeration object does not support any methods, events, or other services.

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

6.8.2 Device and sensor status

The device and sensor status enumeration object allows INR meter-specific errors to be recorded in order to track important troubleshooting information to allow sensor faults and inappropriate use to be determined.

The nomenclature code to identify the enumeration object class is MDC_MOC_VMO_METRIC_ENUM. The object identifier (OID)-Type and bit assignments shall be implemented as described in this subclause. Refer to Table 15 for the set of attributes of this object.

This object is instantiated only in extended configurations. A manager should support the interpretation of this object to enable reporting of these occurrences. An agent should support this object to transmit these occurrences.

Table 15—Device and sensor status enumeration object attributes

Attribute name	Extended configuration	
	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M
Type	{MDC_PART_PHD_DM | MDC_INR_METER_DEV_STATUS}.	M
Metric-Spec-Small	mss-avail-intermittent | mss-avail-stored-data | mss-upd-aperiodic | mss-msmt-aperiodic | mss-acc-agent-initiated.	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C
Base-Offset-Time-Stamp	See IEEE Std 11073-20601a-2010.	R
Enum-Observed-Value-Basic-Bit-Str	See following text.	M

NOTE—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

The device and sensor status object emits only event flags relating to the status of the device; thus, no Unit-Code attribute and no Source-Handle-Reference are required.

Each specific device event is annunciated by setting the appropriate bit in the Enum-Observed-Value-Basic-Bit-Str attribute, as defined in Table 16. It is recommended that the Enum-Observed-Value-Basic-Bit-Str attribute be used as it consumes fewer payload octets than the Enum-Observed-Value-Simple-Bit-Str attribute. If a manager supports the interpretation of this object, it shall be able to interpret the entire set of presented conditions. An agent may implement any subset of these same conditions. Note that a manager shall interpret these bits only within the context of this attribute and only within this device specialization, as other specializations may use corresponding terms for different purposes.

Table 16—Mapping of device, sensor and signal status to object Bit-Str attribute

Device or sensor condition	INRDevStat mnemonic
Agent reports that the battery is low and needs replacing.	inr-device-battery-low
Agent reports that the sensor is malfunctioning or faulting.	inr-sensor-malfunction
Agent reports that there is not enough blood/control solution on the strip.	inr-sensor-sample-size-insufficient
Agent reports that the strip was inserted incorrectly.	inr-sensor-strip-insertion
Agent reports that the strip is not the right type for the device.	inr-sensor-strip-type-incorrect
Agent reports that the reading or value is higher than the sensor can process.	inr-sensor-result-too-high
Agent reports that the reading or value is lower than the sensor can process.	inr-sensor-result-too-low
Agent reports that the ambient temperature is too high for a valid test/result.	inr-sensor-temp-too-high
Agent reports that the ambient temperature is too low for a valid test/result.	inr-sensor-temp-too-low
Agent reports that the reading was interrupted or the strip was pulled too soon.	inr-sensor-read-interrupt
A general device fault has occurred in the agent.	inr-device-gen-fault
Agent reports that the calibration is due.	inr-sensor-calibration due

The specific bit mappings of INRDevStat are defined in Annex B.

6.8.3 Context tester

The precision (and validity) of an INR measurement can be impacted by whom and where the measurement is performed. Table 17 defines the possible testers who may perform the INR measurement.

The nomenclature code to identify the enumeration object class is MDC_MOC_VMO_METRIC_ENUM. This object is instantiated only in extended configurations. A manager should support the interpretation of this object to enable reporting of these occurrences. An agent should support this object to transmit these occurrences.

Table 17—Device and sensor status enumeration object attributes

Attribute name	Extended configuration	
	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M
Type	{MDC_PART_PHD_DM | MDC_CTXT_INR_TESTER }.	M
Metric-Spec-Small	mss-avail-intermittent | mss-avail-stored-data | mss-upd-aperiodic | mss-msmt-aperiodic | mss-acc-agent-initiated.	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C
Base-Offset-Time-Stamp	See IEEE Std 11073-20601a-2010.	R
Enum-Observed-Value-Simple-OID	One of the following nomenclature values shall be used: MDC_CTXT_INR_TESTER_SELF MDC_CTXT_INR_TESTER_HCP MDC_CTXT_INR_TESTER_LAB	M

NOTE—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

6.8.4 Batch code

Table 18 summarizes the attributes of the batch code enumeration object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. The batch code numeric object shall be supported by an INR monitor agent. The batch code shall be specified as a simple string using printable ASCII. It is manufacturer specific.

Table 18—Batch code enumeration object attributes

Attribute name	Extended configuration	
	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M
Type	{MDC_PART_PHD_DM | MDC_BATCHCODE_COAG }.	M
Metric-Spec-Small	mss-avail-intermittent | mss-avail-stored-data | mss-upd-aperiodic | mss-msmt-aperiodic | mss-acc-agent-initiated.	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C
Base-Offset-Time-Stamp	See IEEE Std 11073-20601a-2010.	R
Enum-Observed-Value-Simple-Str	See IEEE Std 11073-20601a-2010.	M

NOTE—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

The batch code enumeration object does not support any methods, events, or other services.

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

6.9 PM-store objects

6.9.1 General

In the context of personal health devices, INR meters are highly portable due to their convenient size and are normally carried around by users so that INR measurements may be taken as needed. More often than not, INR measurements are taken at a time when away from a network and when manager/agent associations cannot be established. It is also common that a given set of measurements made by INR meters may need to be uploaded to more than one manager, for example, in the home and at a medical facility. Any configuration that does not include a PM-store object utilizes agent-initiated event reports to transmit the observations. The use of temporarily stored data as defined in IEEE Std 11073-20601a-2010 is most useful for small numbers of measurements and is subject to automatic deletion during upload.

Alternatively, any configuration with a PM-store for longer term storage shall disable agent-initiated transmission and shall enable access to the PM-store transmissions. As a result, this standard describes a mechanism using PM-store to hold measurements for longer durations. The data held in PM-store objects are deleted by user actions via the manager or user interface on the device and the capacity is limited only by the amount of memory.

6.9.2 Persistent store model

The PM-store model utilizes a PM-segment for each type of object to be persistently stored (see Figure 2). The segment holding INR readings shall be present if the PM-store is implemented. The other segments are optional and hold observations from the further objects that are implemented. Each entry shall include one of the time formats in the segm-entry-header so entries across the different segments can be associated together using a common time stamp. PM-segments are shown as 0..* in Figure 2 to indicate that a new PM-Segment is created whenever the time of the agent is changed.

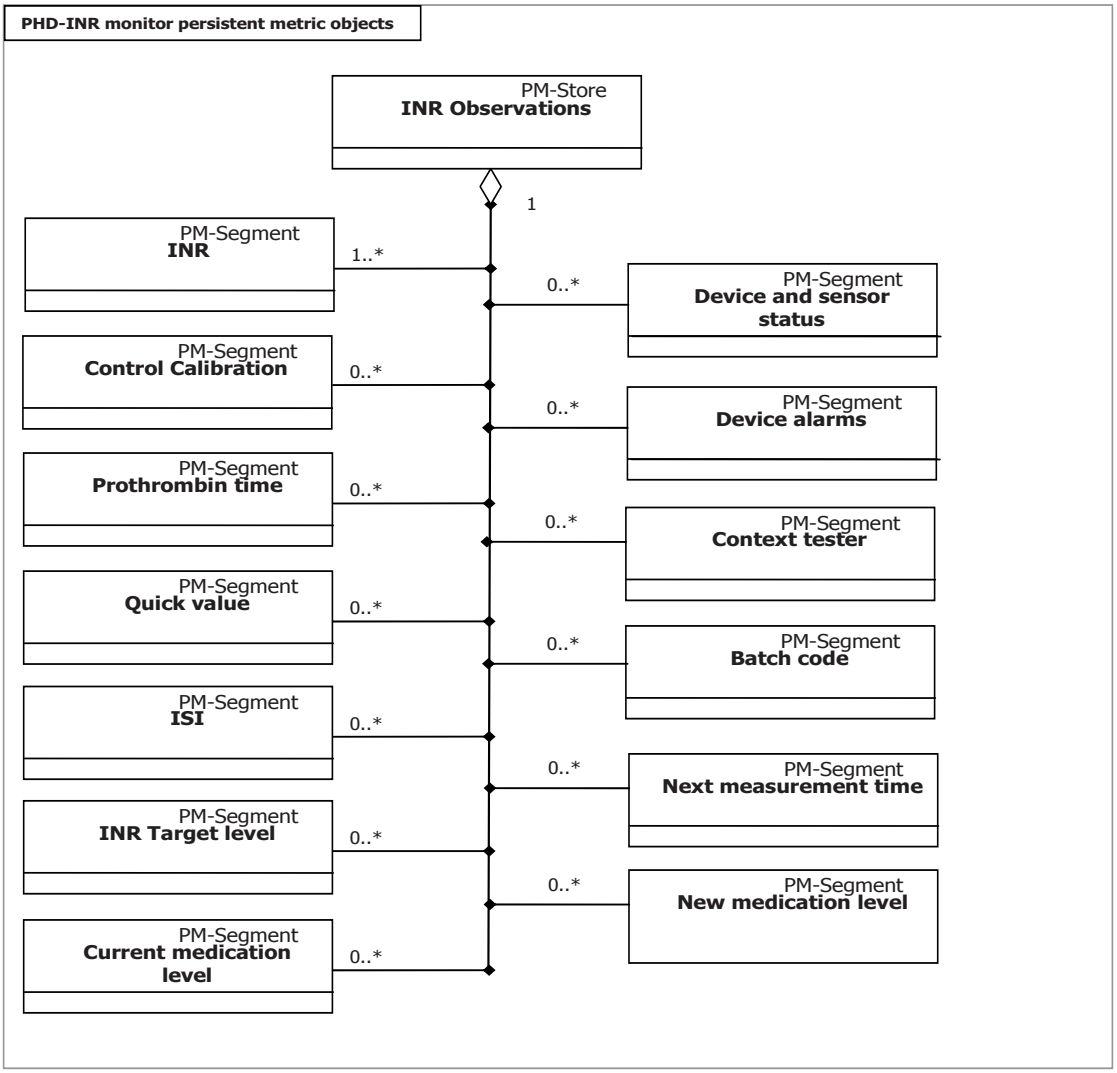

Figure 2—INR monitor—persistent metric store model

6.9.3 PM-store object attributes

Table 19 defines the attributes of the PM-store objects that shall be implemented by the agent. The nomenclature code to identify the PM-store objects is MDC_MOC_VMO_PMSTORE.

Table 19—PM-store object attributes

Attribute name	Extended configuration	
	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M
PM-Store-Capab	See IEEE Std 11073-20601a-2010.	M
Store-Sample-Algorithm	See IEEE Std 11073-20601a-2010.	M
Store-Capacity-Count	See IEEE Std 11073-20601a-2010.	M
Store-Usage-Count	See IEEE Std 11073-20601a-2010.	M
Operational-State	See IEEE Std 11073-20601a-2010.	M
PM-Store-Label	See IEEE Std 11073-20601a-2010.	M
Sample-Period	See IEEE Std 11073-20601a-2010.	NR
Number-Of-Segments	Number dependent on context support or time changes.	M
Clear-Timeout	See IEEE Std 11073-20601a-2010.	M

Some considerations when using the PM-Store-Capab are as follows:

— If the agent creates new segments due to time changes as described in the "Comparable time" clause of IEEE Std 11073-20601a-2010, then pmsc-var-no-of-segm shall be set.

— If the agent is recording episodic data in the PM-store, then the pmsc-epi-seg-entries shall be set.

— The remaining bits are agent specific.

6.9.4 PM-store object methods

Table 20 defines the methods of the PM-store objects.

Table 20—INR monitor PM-store object methods

Service	Subservice type name	Mode	Subservice type (action-type)	Parameters (action-info-args)	Results (action-info-args)
ACTION	Clear-Segments	Confirmed	MDC_ACT_SEG_CLR	SegmSelection	
ACTION	Get-Segment-Info	Confirmed	MDC_ACT_SEG_GET_INFO	SegmSelection	SegmentInfoList
ACTION	Trig-Segment-Data-Xfer	Confirmed	MDC_ACT_SEG_TRIG_XFER	TrigSegmDataXferReq	TrigSegmDataXferRsp

Clear-Segments
This method allows the manager to delete all data entries stored in the PM-segment object.

Get-Segment-Info
This method allows the manager to retrieve the PM-segment attributes.

Trig-Segment-Data-Xfer
This method allows the manager to initiate the transfer of the data entries stored in the PM-segment object.

6.9.5 PM-store object events

Table 21 defines the events sent by the PM-store objects.

Table 21—INR monitor PM-store object events

Service	Subservice type name	Mode	Subservice type (event-type)	Parameters (event-info)	Results (event-reply-info)
EVENT REPORT	Segment-Data-Event	Confirmed	MDC_NOTI_SEGMENT_DATA	SegmentDataEvent	SegmentDataResult

Segment-Data-Event
This event allows the agent to send the data entries stored in the PM-segment object. This event is triggered by the manager using the Trig-Segment-Data-Xfer action.

6.9.6 PM-store object services

6.9.6.1 GET service

The PM-store object supports the GET service to retrieve the values of all PM-store object attributes. The GET service may be invoked as soon as the agent is in the Operating state.

6.9.7 PM-segment objects

Each of the PM-store objects contains a corresponding PM-segment object.

Table 22 defines the attributes of the PM-segment object contained in the PM-store object that represent the stored INR measurements. The nomenclature code to identify the PM-segment object class is MDC_MOC_PM_SEGMENT.

Table 22—Common PM-Segment object attributes

Attribute name	Extended configuration	
	Value	Qual.
Instance Number	See IEEE Std 11073-20601a-2010.	M
PM-Segment-Entry-Map	See IEEE Std 11073-20601a-2010.	M
PM-Seg-Person-Id	See IEEE Std 11073-20601a-2010.	C
Sample-Period	See IEEE Std 11073-20601a-2010.	C
Operational-State	See IEEE Std 11073-20601a-2010.	M
Segment-Label	See IEEE Std 11073-20601a-2010.	M
Segment-Start-BO-Time	See IEEE Std 11073-20601a-2010.	M
Segment-End-BO-Time	See IEEE Std 11073-20601a-2010.	M
Segment-Date-and-Time-Adjustment	See IEEE Std 11073-20601a-2010.	C
Segment-Usage-Count	See IEEE Std 11073-20601a-2010.	M
Segment-Statistics	See IEEE Std 11073-20601a-2010.	O
Fixed-Segment-Data	Segment data transferred as an array of entries in a format as specified in the PM-Segment-Entry-Map attribute.	M
Confirm-Timeout	See IEEE Std 11073-20601a-2010.	O
Transfer-Timeout	See IEEE Std 11073-20601a-2010.	M

The Fixed-Segment-Data attribute stores the actual measurements or context logs. When the Fixed-Segment-Data attribute is transmitted, all entries in the event report are formatted according to the PM-Segment-Entry-Map. Each entry stores a single sample point, which may consist of a set of attributes.

6.10 Scanner objects

Scanner objects are not required by this standard.

6.11 Class extension objects

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

6.12 INR monitor information model extensibility rules

The INR monitor domain information model of this standard may be extended by including vendor-specific metrics and attributes as required. For example, a vendor might require including an INR rate of change measurement. Any object or attribute extensions implemented should follow the guidelines of this standard as closely as possible.

An INR monitor agent having a configuration with extensions beyond the standard configuration, as specified in this standard, shall use a configuration ID in the range of IDs reserved for extended configurations (see IEEE Std 11073-20601a-2010).

7. INR monitor service model

7.1 General

The service model defines the conceptual mechanisms for data exchange services. These 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. See IEEE Std 11073-20601a-2010 for a detailed description of the personal health device service model. Subclauses 7.2 and 7.3 define the specifics of object access and event reporting services for an INR monitor agent according to this standard.

7.2 Object access services

The object access services of IEEE Std 11073-20601a-2010 are used to access the objects defined in the domain information model of the INR monitor.

The following generic object access services are supported by an INR monitor agent according to this standard:

— GET service: used by the manager to retrieve the values of the agent MDS object attributes and the agent PM-Store object attributes. The list of INR monitor MDS object attributes is given in 6.5.4.1, and the PM-Store object is given in 6.9.3.

— SET service: used by the manager to set the values of the agent object attributes. There are no settable attributes defined for the MDS object of an INR monitor agent according to this standard. The list of settable attributes for the International Normalized Ratio (INR) monitor PM-Store object is given in 6.9.3.

— Event report service: used by the agent to send configuration reports and measurement data to the manager. The list of event reports for the INR monitor device specialization is given in 6.5.3 and 6.9.5.

— Action service: used by the manager to invoke actions (or methods) supported by the agent. An example is Set-Base-Offset-Time action, which is used to set a real-time clock with the time at the agent.

Table 23 summarizes the object access services described in this standard.

Table 23—INR monitor MDS object access services

Service	Subservice type name	Mode	Subservice type	Parameters	Result	Remarks
GET	<na>	<implied Confirmed>	<na>	GetArgumentSimple = (obj-handle = 0), attribute-id-list <*optional*>	GetResultSimple = (obj-handle = 0), attribute-list	Allows the manager to retrieve the value of an attribute of an object in the agent.
EVENT REPORT	MDS-Configuration-Event	Confirmed	MDC_NOTI_CONFIG	ConfigReport	ConfigReportRsp	Configuration Report to inform manager of the configuration of the agent.
	MDS-Scan-Report-Var	Confirmed	MDC_NOTI_SCAN_REPORT_VAR	ScanReportInfoVar	—	Data Report to provide dynamic data to manager for some or all of the agent's objects in variable format.
	MDS-Scan-Report-Fixed	Confirmed	MDC_NOTI_SCAN_REPORT_FIXED	ScanReportInfoFixed	—	Data Report to provide dynamic data to manager for some or all of the agent's objects in fixed format.
	MDS-Scan-Report MP-Var	Confirmed	MDC_NOTI_SCAN_REPORT_MP_VAR	ScanReportInfoMPVar	—	This is the same as MDS-Dynamic-Data-Update-Var, but allows inclusion of data from multiple people.
	MDS-Scan-Report-MP-Fixed	Confirmed	MDC_NOTI_SCAN_REPORT_MP_FIXED	ScanReportInfoMPFixed	—	This is the same as MDS-Dynamic-Data-Update-Fixed, but allows inclusion of data from multiple people.
ACTION	Set-Base-Offset-Time	Confirmed	MDC_ACT_SET_BO_TIME	SetBOTimeInvoke	—	Manager method to invoke the agent to set time to requested value.

7.3 Object access event report services

The event report service (see Table 23) is used by the agent to report its information (e.g., measurements). Event reports in this standard are a property of the MDS object and the PM_Store object as defined in 6.9.5. The event reports used in this standard are defined in IEEE Std 11073-20601a-2010.

The following conditions apply for an INR monitor agent according to this standard:

— Event reports shall be used in confirmed mode.

— Agent-initiated mode shall be supported for measurement data transmission.

An INR monitor agent, which is designed to operate in an environment where data may be collected from multiple people, may use one of the multiperson event report styles to transmit all the data from each person in a single event. If this functionality is not required, the agent may use the single-person event report styles, which have reduced overhead.

A manager shall support both single-person and multiple-person event reports. An INR monitor agent may support either one or both single-person and multiple-person event reports. The formats for single- and multiple-person reports are described in IEEE Std 11073-20601a-2010.

8. INR monitor communication model

8.1 Overview

This clause describes the general communication model and procedures of the INR monitor agent as defined in IEEE Std 11073-20601a-2010. Therefore, the respective parts of IEEE Std 11073-20601a-2010 are not reproduced; rather the specific choices and restrictions with respect to optional elements (e.g., objects, attributes, and actions) and specific extensions (e.g., nomenclature terms) are specified.

For an illustrative overview of the various message transactions during a typical measurement session, see the sequence diagram for the example use case in Annex D and the corresponding protocol data unit (PDU) examples in Annex E.

8.2 Communications characteristics

In this subclause, limits on the size of an application protocol data unit (APDU) transmitted or to be received by an INR monitor agent are defined. Small limits allow for simple implementations in terms of low cost and complexity.

An INR monitor agent implementing only this device specialization shall not transmit any APDU larger than N_{tx} and shall be capable of receiving any APDU up to a size of N_{rx}. For this standard, N_{tx} shall be 896 octets and N_{rx} shall be 224 octets.

For an INR monitor agent implementing functions from other device specializations, an upper bound estimation of the APDU sizes brings the following: An agent shall not transmit any APDU larger than the sum of N_{tx} of all the device specializations implemented and shall be capable of receiving any APDU up to the sum of N_{rx} of all the device specializations implemented. If these numbers are higher than the maximum size determined in IEEE Std 11073-20601a-2010, the latter shall be applied.

In case the APDU size limit does not allow for the inclusion of a certain amount of multiple pending measurements at the agent, they shall be sent using multiple event reports. See 8.5.3 for the maximum number of measurements allowed for inclusion in a single event report.

8.3 Association procedure

8.3.1 General

Unless otherwise stated, the association procedure for an agent and manager according to this standard shall be pursued as specified in IEEE Std 11073-20601a-2010.

8.3.2 Agent procedure—association request

In the association request sent by the agent to the manager:

- The version of the association procedure used by the agent shall be set to assoc-version1 (i.e., *assoc-version* = 0x80000000).
- The DataProtoList structure element of the data protocol identifier shall be set to data-proto-id-20601 (i.e., *data-proto-id* = 0x5079).
- The *data-proto-info* field shall contain a PhdAssociationInformation structure that shall contain the following parameter values:

    1) The agent shall support protocol-version2. Support for any other version may be indicated by setting additional bits. When protocols higher than protocol-version2 are used, the agent shall continue to use only features as specified in this standard. When protocols lower than protocol-version2 are used, the agent shall use only features in that protocol.
    2) At least the MDERs shall be supported (i.e., *encoding-rules* = 0x8000).
    3) The version of the nomenclature used shall be set to nom-version1 (i.e., *nomenclature-version* = 0x80000000).
    4) The field *functional-units* may have the test association bits set but shall not have any other bits set.
    5) The field *system-type* shall be set to sys-type-agent (i.e., *system-type* = 0x00800000).
    6) The *system-id* field shall be set to the value of the System-Id attribute of the MDS object of the agent. The manager may use this field to determine the identity of the INR monitor with which it is associating and, optionally, to implement a simple access restriction policy.
    7) The *dev-config-id* field shall be set to the value of the Dev-Configuration-Id attribute of the MDS object of the agent.
    8) If the agent supports only the INR monitor specialization, then the field indicating the data request modes (*data-req-mode-capab*) supported by the INR monitor agent shall be set to *data-req-supp-init-agent.*
    9) If the agent supports only the INR monitor specialization, then *data-req-init-manager-count* shall be set to zero, and *data-req-init-agent-count* shall be set to 1.

8.3.3 Manager procedure—association response

In the association response message sent by the manager:

- The *result* field shall be set to an appropriate response from those defined in IEEE Std 11073-20601a-2010. For example, if all other conditions of the association protocol are satisfied, *accepted* is returned when the manager recognizes the *dev-config-id* of the agent and *accepted-unknown-config* otherwise.

— In the DataProtoList structure element, the data protocol identifier shall be set to data-proto-id-20601 (i.e., *data-proto-id* = 0x5079).

— The *data-proto-info* field shall be filled in with a PhdAssociationInformation structure that shall contain the following parameter values:

1) A manager following this specialization shall support *protocol-version2*. A manager may support additional higher protocol versions and select them if offered by an agent.
2) The manager shall respond with a single selected encoding rule that is supported by both agent and manager. The manager shall support at least the MDERs.
3) The version of the nomenclature used shall be set to nom-version1 (i.e., *nomenclature-version* = 0x80000000).
4) The field *functional-units* shall have all bits reset except for those relating to a test association.
5) The field *system-type* shall be set to sys-type-manager (i.e., *system-type* = 0x80000000).
6) The *system-id* field shall contain the unique system ID of the manager device, which shall be a valid EUI-64 type identifier.
7) The field *dev-config-id* shall be manager-config-response (0).
8) The field *data-req-mode-capab* shall be 0.
9) If the agent supports only the INR specialization, *data-req-init-agent-count* shall be set to 0 and *data-req-init-manager-count* shall be set to 0.

8.4 Configuring procedure

8.4.1 General

The agent enters the Configuring state if it receives an association response of accepted-unknown-config. In this case, the configuration procedure as specified in IEEE Std 11073-20601a-2010 shall be followed. Subclause 8.4.2 specifies the configuration notification and response messages for an INR monitor agent with standard configuration ID 1800 (0x0708). Normally, a manager would already know the standard configuration. However, for the purposes of this example, it does not.

8.4.2 INR monitor—standard configuration

8.4.2.1 Agent procedure

The agent performs the configuration procedure using a "Remote Operation Invoke | Confirmed Event Report" message with an MDC_NOTI_CONFIG event to send its configuration to the manager (see IEEE Std 11073-20601a-2010). The ConfigReport structure is used for the *event-info* field (see Table 3). For an INR monitor agent with standard configuration ID 1800 (0x708), the format and contents of the configuration notification message are as follows:

```
0xE7 0x00          APDU CHOICE Type (PrstApdu)
0x00 0x44          CHOICE.length = 68
0x00 0x42          OCTET STRING.length = 66
0x00 0x02          invoke-id = 2 (start of DataApdu. MDER encoded.)
0x01 0x01          CHOICE(Remote Operation Invoke | Confirmed Event Report)
0x00 0x3C          CHOICE.length = 60
0x00 0x00          obj-handle = 0 (MDS object)
```

0xFF 0xFF 0xFF 0xFF	event-time (set to 0xFFFFFFFF if RelativeTime is not supported)
0x0D 0x1C	event-type = MDC_NOTI_CONFIG
0x00 0x32	event-info.length = 50 (start of ConfigReport)
0x07 0x08	config-report-id (Dev-Configuration-Id value)
0x00 0x01	config-obj-list.count = 1 Measurement objects will be “announced”
0x00 0x2C	config-obj-list.length = 44
0x00 0x06	obj-class = MDC_MOC_VMO_METRIC_NU
0x00 0x01	obj-handle = 1 (→ 1st Measurement is INR)
0x00 0x04	attributes.count = 4
0x00 0x24	attributes.length = 36
0x09 0x2F	attribute-id = MDC_ATTR_ID_TYPE
0x00 0x04	attribute-value.length = 4
0x00 0x02 0x72 0x04	MDC_PART_SCADA | MDC_RATIO_INR_COAG
0x0A 0x46	attribute-id = MDC_ATTR_METRIC_SPEC_SMALL
0x00 0x02	attribute-value.length = 2
0xF0 0x40	intermittent, stored data, upd & msmt aperiodic, agent init, measured
0x09 0x96	attribute-id = MDC_ATTR_UNIT_CODE
0x00 0x02	attribute-value.length = 2
0x19 0xD0	MDC_DIM_INR
0x0A 0x55	attribute-id = MDC_ATTR_ATTRIBUTE_VAL_MAP
0x00 0x0C	attribute-value.length = 12
0x00 0x02	AttrValMap.count = 2
0x00 0x08	AttrValMap.length = 8
0x0A 0x4C 0x00 0x02	MDC_ATTR_NU_VAL_OBS_BASIC, 2
0x0A 0x82 0x00 0x08	MDC_ATTR_TIME_STAMP_BO, 8

8.4.2.2 Manager procedure

The manager shall respond to a configuration notification message using a “Remote Operation Response | Confirmed Event Report” data message with an MDC_NOTI_CONFIG event using the ConfigReportRsp structure for the *event-info* field (see Table 3). As a response to the standard configuration notification message in 8.4.2.1, the format and contents of the manager’s configuration notification response message are as follows:

0xE7 0x00	APDU CHOICE Type (PrstApdu)
0x00 0x16	CHOICE.length = 22
0x00 0x14	OCTET STRING.length = 20
0x00 0x02	invoke-id = 0x0002 (mirrored from invocation)
0x02 0x01	CHOICE (Remote Operation Response | Confirmed Event Report)
0x00 0x0E	CHOICE.length = 14
0x00 0x00	obj-handle = 0 (MDS object)
0x05 0x14 0xDB 0x12	currentTime
0x0D 0x1C	event-type = MDC_NOTI_CONFIG
0x00 0x04	event-reply-info.length = 4
0x07 0x08	ConfigReportRsp.config-report-id = 1800
0x00 0x00	ConfigReportRsp.config-result = accepted-config

8.5 Operating procedure

8.5.1 General

Measurement data and status information are communicated from the INR monitor agent during the Operating state. If not stated otherwise, the operating procedure for an INR monitor agent of this standard shall be as specified in IEEE Std 11073-20601a-2010.

8.5.2 GET INR monitor MDS attributes

See Table 4 for a summary of the GET service.

If the *attribute-id-list* field in the roiv-cmip-get service message is empty, the INR monitor agent shall respond with a rors-cmip-get service message in which the attribute-list contains a list of all implemented attributes of the MDS object.

If the manager requests specific MDS object attributes, indicated by the elements in *attribute-id-list*, and the agent supports this capability, the INR agent shall respond with a rors-cmip-get service message in which the attribute-list contains a list of the requested attributes of the MDS object that are implemented. It is not required for an INR monitor agent to support this capability. If this capability is not implemented, the INR monitor agent shall respond with a "Remote Operation Error Result" (roer) service message (see IEEE Std 11073-20601a-2010) with the error-value field set to not_allowed_by_object (24).

8.5.3 Measurement data transmission

See Table 3 for a summary of the event report services available for measurement data transfer.

Measurement data transfer for an INR monitor agent of this standard shall always be initiated by the INR monitor (see agent-initiated measurement data transmission in IEEE Std 11073-20601a-2010). To limit the amount of data being transported within an APDU, the INR monitor agent shall not include more than 25 temporarily stored measurements in a single event report. If more than 25 pending measurements are available for transmission, they shall be sent using multiple event reports. If multiple INR measurements are available, up to 25 measurements should be transmitted within a single event report. Alternatively, they may be transmitted using a single event report for each INR measurement. However, the former strategy is recommended to reduce overall message size and power consumption.

8.6 Time synchronization

Time synchronization between an INR monitor agent and a manager may be used to coordinate the clocks used when reporting physiological events. Note that the mechanism for synchronizing an agent to a manager is outside the scope of this standard. If time synchronization is used, then this shall be reported in the Mds-Time-Info attribute of the MDS object.

9. Test associations

The test association provides a manufacturer the mechanism to test or demonstrate features of a product in a comprehensive manner. This clause defines the behavior of the standard INR monitor agent during a test association. Support for test association is optional.

9.1 Behavior with standard configuration

An agent or manager entering a test association using the configuration ID for the standard INR monitor device of this standard shall enter the Operating state in test mode. When in test mode, where possible, this should be indicated visually to any user. Normal functionality shall be suspended and any test data generated shall not be processed by the device as physiological data.

The INR monitor agent shall send a single simulated INR value of 1.99 INR units (a value never seen in normal usage and outside normal range) within 30 s of entering the Operating state. If the measurement-status attribute of the numeric object is implemented, then the test-data bit shall be set.

The test association is terminated in a manner consistent with the agent's normal behavior for terminating an association.

9.2 Behavior with extended configurations

This specification does not define a test association that uses an extended configuration.

10. Conformance

10.1 Applicability

This standard shall be used in conjunction with IEEE Std 11073-20601a-2010.

An implementation or a system can conform to the following elements of this standard:

— Domain information model class hierarchy and object definitions (object attributes, notifications, methods and data type definitions)

— Nomenclature code values

— Protocol and service models

— Communication service model (association and configuration)

10.2 Conformance specification

This standard offers levels of conformance with respect to strict adherence to the standard device and the use of extensions for:

— Information model of a specific device

— Use of attributes, value ranges, and access methods

A vendor shall specify the level of conformance for an implementation based on this standard and provide details of the way in which the definitions of this standard and any extensions are applied.

Specifications shall be provided in the form of a set of implementation conformance statements (ICS) as detailed in 10.4.

This standard is used in conjunction with IEEE Std 11073-20601a-2010. It is recommended that the ICS for this standard be created first so that the ICS created for IEEE Std 11073-20601a-2010 may refer to the ICS for this standard where applicable.

10.3 Levels of conformance

10.3.1 General

This standard defines the following levels of conformance.

10.3.2 Conformance level 1: Base conformance

The application uses elements of the information, service, and communication models (object hierarchy, actions, event reports, and data type definitions) and the nomenclature scheme defined in IEEE Std 11073-20601a-2010 and the IEEE Std 11073-104zz documents. All mandatory features defined in the object definition tables and in the ICS tables are implemented. Furthermore, any conditional, recommended, or optional features that are implemented shall follow the requirements in IEEE Std 11073-20601a-2010 and ISO/IEEE P11073-104zz.

10.3.3 Conformance level 2: Extended nomenclature (ASN.1 and/or ISO/IEEE 11073-10101:2004 [B8])

Conformance level 2 meets conformance level 1 but also uses or adds extensions in at least one of the information, service, or nomenclature models. Extensions to nomenclature codes shall conform to the ISO/IEEE 11073-10101:2004 [B8] framework and lie within the private nomenclature extension range (0xF000 – 0xFFFF).

Extensions to the information or service models shall be fully defined using ASN.1 where appropriate and have their behavior fully described following the framework of IEEE Std 11073-20601a-2010 and/or ISO/IEEE 11073-20101:2004 [B10]. All extensions shall be specified and include reference to the definition for the extension, or where no publicly available reference is available, the definition of the extension should be appended to the conformance statement.

10.4 Implementation conformance statements

10.4.1 General format

The ICSs are provided as an overall conformance statement document that comprises a set of tables in the form given by the templates in the following clauses.

Each ICS table has the following columns:

Index	Feature	Reference	Req/Status	Support	Comment

The table column headings have the following meaning:

— Index: an identifier (e.g., a tag) of a specific feature.

— Feature: briefly describes the characteristic for which a conformance statement is being made.

— Reference: to the clause/paragraph within this document or an external source for the definition of the feature (may be empty).

— Req/Status: specifies the conformance requirement (e.g., mandatory or recommended)—in some cases, this standard does not specify conformance requirements but requests the status of a particular feature be provided.

— Support: specifies the presence or absence of a feature and any description of the characteristics of the feature in the implementation. This column is to be filled out by the implementer.

— Comment: contains any additional information on the feature. This column is to be filled out by the implementer.

Subclauses 10.4.2 through 10.4.6 specify the format of the specific ICS tables.

10.4.2 General implementation conformance statement

The general ICS specifies the versions/revisions that are supported by the implementation and high-level system behavior.

Table 24 shows general ICSs.

Table 24—11073-10418 general ICS table

Index[a]	Feature	Reference	Req./Status	Support	Comment
GEN 11073-10418-1	Implementation Description	—	Identification of the device/ application. Description of functionality.		
GEN 11073-10418-2	Standards followed and their revisions	(standard documents)	(set of existing revisions)	(set of supported revision)	
GEN 11073-10418-3	Nomenclature document used and revision	(standard documents)	(set of existing revisions)	(set of supported revisions)	
GEN 11073-10418-4	Conformance Adherence - Level 1 -	See 10.3.2	Base conformance declaration that device meets the following IEEE Std 11073-10418 conformance requirements: a) All mandatory requirements shall be implemented. b) If implemented, conditional, recommended, and optional requirements shall conform to standard.	Yes/No (No is not expected as No implies that the implementation is non-conformant)	
GEN 11073-10418-5	Conformance Adherence - Level 2 -	See 10.3.3	In addition to GEN 11073-10418-4, if the device implements extensions and/or additions, they shall conform to nomenclature codes from ASN.1 and/or 10101 framework. These extensions should also be defined in ICS tables pointing toward their reference.	Yes/No	

Index[a]	Feature	Reference	Req./Status	Support	Comment
GEN 11073-10418-6	Object Containment Tree	See 6.3	Provide Object Containment Diagram showing relations between object instances used by the application. A conforming implementation uses only object relations as defined in the DIM.		
GEN 11073-10418-7	Nomenclature document used and revision	(standard documents)	(set of existing revisions)	(set of supported revision)	
GEN 11073-10418-8	Data Structure Encoding	—	—	description of encoding method(s) for ASN.1 data structures	
GEN 11073-10418-9	Use of Private Objects	—	Does the implementation use objects that are not defined in the DIM?	Yes/No (If yes: explain in Table 25)	
GEN 11073-10418-10	Use of Private Nomenclature Extensions	—	Does the implementation use private extensions to the nomenclature (i.e., 0xF000-0xFFFF codes from ISO/IEEE 11073-10101:2004 [B8])? Private Nomenclature extensions are only allowed if the standard nomenclature does not include the specific terms required by the application.	Yes/No (If yes: explain in the Table 28)	
GEN 11073-10418-11	11073-20601 Conformance		Provide the conformance report required by IEEE Std 11073-20601a-2010.		

[a] The prefix GEN11073-10418- is used for the index in the general ICSs table.

10.4.3 DIM MOC implementation conformance statement

The DIM MOC ICS defines which objects are implemented. Information on each object shall be provided as a separate row in the template of Table 25.

Table 25—Template for DIM MOC ICS table

Index	Feature	Reference	Req./Status	Support	Comment
MOC-*n*	Object description	Reference to the clause in the standard or other location where the object is defined.	Implemented	Specify restrictions, e.g., maximum number of supported instances.	

The *n* in the Index column should be the object handle for implementations that have predefined objects. Otherwise the Index column shall simply be a unique number (1..*m*).

All private objects should be specified and include either a reference to the definition for the object, or where no publicly available reference is available, the definition of the object should be appended to the conformance statement.

The Support column should indicate any restrictions for the object implementation.

An object containment diagram (class instance diagram) should be provided as part of the DIM MOC ICS.

10.4.4 MOC attribute ICS

The MOC attribute ICS defines which attributes, including any inherited attributes, are used/supported in each object of an implementation. Information on each attribute of an object shall be provided as a separate row in the template of Table 26. A separate MOC attribute ICS shall be provided for each object.

Table 26—Template for MOC attribute ICS table

Index	Feature	Reference	Req./Status	Support	Comment
ATTR-*n-x*	Attribute Name. Extended attributes shall include the attribute ID also.	Fill in the reference to the ASN.1 structure if the attribute is not defined in this standard.	M = Mandatory / C = Conditional / R = Recommended / O = Optional (as per definition in Attribute Definition Tables)	Implemented? Yes/No Static/Dynamic Specify restrictions, (e.g., value ranges). Describe how attribute is accessed (e.g., Get, Set, sent in config event report, sent in a data event report). Describe any specific restrictions.	

The Support column shall specify: whether the attribute is implemented; for extension attributes, whether the attribute value is static or dynamic; any value ranges; restrictions on attribute access or availability; and any other information.

The *n* in the Index column refers to the ID of the managed object for which the table is supplied (i.e., the index of the managed object as specified in the MOC ICS). There is one separate table for each supported managed object.

The *x* in the Index column is a unique serial number (1..*m*).

10.4.5 MOC notification implementation conformance statement

The MOC notification ICS specifies all implemented notifications (typically in the form of the event report service) that are emitted by the agent. Table 27 provides a template for use. One table has to be provided for each object that supports special object notifications. One row of the table shall be used for each notification.

Table 27—Template for MOC notification ICS table

Index	Feature	Reference	Req./Status	Support	Comment
NOTI-*n*-*x*	Notification Name and Notification ID	Reference to the clause in the standard or other location where the event is defined.		The Support column shall specify how the notification is sent and any restrictions.	

The *n* in the Index column refers to the ID of the managed object for which the table is supplied (i.e., the index of the managed object as specified in the POC ICS). There is one separate table for each managed object that supports specific object notifications (i.e., events).

The *x* in the Index column is a unique serial number (1..*m*).

All private notifications should be specified and include reference to the definition for the notification. Where no publicly available reference is available, the definition of the notification should be appended to the conformance statement.

10.4.6 MOC nomenclature conformance statement

The MOC nomenclature ICS specifies all nonstandard nomenclature codes that are utilized by the agent. Table 28 provides a template for use. One row of the table is to be used for each nomenclature element.

Table 28—Template for MOC nomenclature ICS table

Index	Feature	Reference	Req./Status	Support	Comment
NOME-n	Nomenclature Name and Nomenclature value	Reference to the clause in the standard or other location where the nomenclature is defined or used.		Describe how the nomenclature is used. Describe any specific restrictions.	

The *n* in the Index column is a unique serial number (1..*m*).

Annex A

(informative)

Bibliography

Bibliographical references are resources that provide additional or helpful material but do not need to be understood or used to implement this standard. Reference to these resources is made for informational use only.

[B1] IEC 60601-1:2005, Ed. 3, Medical electrical equipment—Part 1: General requirements for basic safety and essential performance.[8]

[B2] IEC 60601-1-1:2000, Ed. 2, Medical electrical equipment—Part 1-1: General requirements for safety—Collateral standard: Safety requirements for medical electrical systems.

[B3] IEC 60601-1-2:2007, Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance—Collateral standard: Electromagnetic compatibility—Requirements and tests.

[B4] IEC 60601-2, Medical electrical equipment—Part 2: Particular requirements for the basic safety and essential performance for specific device. (See the entire series of standards, Part 2-1 through Part 2-51.)

[B5] IEC 62304:2006/EN 62304:2006, Medical device software—Software life-cycle processes.[9]

[B6] IEC 80001-1:2010, Application of risk management for IT-networks incorporating medical devices—Part 1: Roles, responsibilities, and activities.

[B7] ISO 14971:2007, Medical devices—Application of risk management to medical devices.[10]

[B8] ISO/IEEE 11073-10101:2004, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.[11]

[B9] ISO/IEEE 11073-10201:2004, Health informatics—Point-of-care medical device communication—Part 10201: Domain information model.

[B10] ISO/IEEE 11073-20101:2004, Health informatics—Point-of-care medical device communication—Part 20101: Application profile—Base standard.

[B11] ITU-T Rec. X.680-2002, Information technology—Abstract Syntax Notation One (ASN.1): Specification of basic notation.[12]

[8] IEC publications are available from the Sales Department of the International Electrotechnical Commission, Case Postale 131, 3 rue de Varembé, CH-1211, Genève 20, Switzerland/Suisse (http://www.iec.ch/). IEC publications are also available in the United States from the Sales Department, American National Standards Institute, 11 West 42nd Street, 13th Floor, New York, NY 10036, USA.

[9] EN publications are available from the European Committee for Standardization (CEN), 36, rue de Stassart, B-1050 Brussels, Belgium (http://www.cenorm.be).

[10] ISO publications are available from the ISO Central Secretariat, Case Postale 56, 1 rue de Varembé, CH-1211, Genève 20, Switzerland/ Suisse (http://www.iso.ch/). ISO publications are also available in the United States from the Sales Department, American National Standards Institute, 11 West 42nd Street, 13th Floor, New York, NY 10036, USA (http://www.ansi.org/).

[11] ISO/IEEE publications are available from the ISO Central Secretariat, 1, ch. de la Voie-Creuse, Case Postale 56, CH-1211, Geneva 20, Switzerland (http://www.iso.ch/). ISO/IEEE publications are also available in the United States from the Institute of Electrical and Electronics Engineers, 445 Hoes Lane, Piscataway, NJ 08854-4141, USA (http://standards.ieee.org/).

[12] ITU publications are available from the International Telecommunications Union, Place des Nations, 1211 Geneva 20, Switzerland (http://www.itu.int/). This specification may be found specifically at http://www.itu.int/ITU-T/studygroups/com17/languages/X.680-0207.pdf.

Annex B

(normative)

Any additional ASN.1 definitions

Device and sensor status bit mapping

The extension to the enumeration class for device and sensor annunciation requires the following ASN.1 structure definition:

```
INRDevStat::= BITS-16 {
                        inr-device-battery-low(0),
                        inr-sensor-malfunction(1),
                        inr-sensor-sample-size-insufficient(2),
                        inr-sensor-strip-insertion(3),
                        inr-sensor-strip-type-incorrect(4),
                        inr-sensor-result-too-high(5),
                        inr-sensor-result-too-low(6),
                        inr-sensor-temp-too-high(7),
                        inr-sensor-temp-too-low(8),
                        inr-sensor-read-interrupt(9),
                        inr-device-gen-fault(10),
                        inr-sensor-calibration-due(11)
                    }
```

Annex C

(normative)

Allocation of identifiers

This annex contains the nomenclature codes (Table C.1 through Table C.5) used in this document and not found in IEEE Std 11073-20601a-2010. For those not contained in this annex, the normative definition is found in IEEE Std 11073-20601a-2010.

The format used here follows that of ISO/IEEE 11073-10101:2004 [B8].

Table C.1—Device profiles nomenclature and codes

Systematic name	Common term	Reference ID	Code
Profile | Device | Coagulation	International Standardized Ratio	MDC_DEV_SPEC_PROFILE_COAG	4118

The terms in Table C.2 are deprecated as these are incorrect blood chemistry terms. Serum is the part that remains following coagulation, and therefore, it cannot have coagulation measurements.

Table C.2—Deprecated nomenclature and codes for plasma coagulation measurements

Systematic name	Common term	Reference ID	Code
Ratio | Coagulation | Serum | Blood Chemistry	Serum coagulation ratio	MDC_RATIO_SERUM_COAG	28980
Duration | Coagulation | Serum | Blood Chemistry	Serum coagulation time	MDC_TIME_PD_SERUM	28988

Table C.3—Nomenclature and codes for INR measurements

Systematic name	Common term	Reference ID	Code
Ratio | Coagulation | Plasma | Blood Chemistry	Coagulation ratio – INR	MDC_RATIO_INR_COAG	29188
Duration | Coagulation | Plasma | Blood Chemistry	Coagulation time – prothrombin time	MDC_TIME_PD_COAG	29192
Quick value | Coagulation | Plasma | Blood Chemistry	Coagulation quick value	MDC_QUICK_VALUE_COAG	29196
ISI | Coagulation | Plasma | Blood Chemistry	International Sensitivity Index	MDC_ ISI_COAG	29200
Control | Coagulation | Plasma | Blood Chemistry	Control calibration of INR	MDC_COAG_CONTROL	29204

Table C.4—Nomenclature and codes for INR status and context

Systematic name	Common term	Reference ID	Code
Batch code | Coagulation | Plasma | Blood Chemistry	INR Batch code	MDC_ BATCHCODE_COAG	29300
Status | value | Functional Status | Device	Device status	MDC_INR_METER_DEV_STATUS	29301
Target level| Coagulation | Plasma | Blood Chemistry	INR target level	MDC_ TARGET_LEVEL_COAG	29304
Current medication | Coagulation | Plasma | Blood Chemistry	INR current medication	MDC_ MED_ CURRENT_COAG	29308
New medication | Coagulation | Plasma | Blood Chemistry	INR new medication	MDC_ MED_ NEW_COAG	29312
Test context | Coagulation | Blood Chemistry	Tester	MDC_CTXT_INR_TESTER	29316
Self | Test context | Coagulation | Blood Chemistry	Self test	MDC_CTXT_INR_TESTER_SELF	29317
Health Care Professional | Test context | Coagulation | Blood Chemistry	Health care professional tester	MDC_CTXT_INR_TESTER_HCP	29318
Laboratory Test context | Coagulation | Blood Chemistry	Laboratory based test	MDC_CTXT_INR_TESTER_LAB	29319

Table C.5—Vital signs units of measurement

Dimension	Unit of measurement	Symbol (not normative)	Reference ID	Code
INR units	INR units		MDC_DIM_INR	6608

```
/*****************************************************************************
* From Infrastructure (MDC_PART_INFRA) (8)
*****************************************************************************/
#define MDC_DEV_SPEC_PROFILE_COAG          4118  /*                          */

/*****************************************************************************
* From Medical supervisory control and data acquisition (MDC_PART_SCADA) (2)
*****************************************************************************/
#define MDC_RATIO_INR_COAG                 29188  /*                         */
#define MDC_TIME_PD_COAG                   29192  /*                         */
#define MDC_QUICK_VALUE_COAG               29196  /*                         */
#define MDC_ISI_COAG                       29200  /*                         */
#define MDC_COAG_CONTROL                   29204  /*                         */

/*****************************************************************************
* From Personal Health Device Disease Management (MDC_PART_PHD_DM) (128)
*****************************************************************************/
#define MDC_BATCHCODE_COAG                 29300  /*                         */
#define MDC_INR_METER_DEV_STATUS           29301  /*                         */
#define MDC_TARGET_LEVEL_COAG              29304  /*                         */
#define MDC_MED_CURRENT_COAG               29308  /*                         */
#define MDC_MED_NEW_COAG                   29312  /*                         */
#define MDC_CTXT_INR_TESTER                29316  /*                         */
#define MDC_CTXT_INR_TESTER_SELF           29317  /*                         */
#define MDC_CTXT_INR_TESTER_HCP            29318  /*                         */
#define MDC_CTXT_INR_TESTER_LAB            29319  /*                         */
```

```
/**************************************************************************
* From Dimensions (MDC_PART_DIM) (4)
**************************************************************************/
#define MDC_DIM_MILLI_G                 1746  /* mg                        */
#define MDC_DIM_INR                     6608  /* INR units                 */
#define MDC_DIM_PERCENT                 544   /* Percent                   */
```

Annex D

(informative)

Message sequence examples

Figure D.1 shows a sequence diagram of the messaging procedure corresponding to the following use case. The user of an INR monitor agent device intends to connect it to a manager device for the first time. The INR is capable of performing INR measurements.

a) When the user connects the INR monitor, the manager does not recognize the agent's configuration and sends a response to the agent's association request with the result *accepted-unknown-config*. See E.2.2.2 and E.2.2.1 for the corresponding PDU examples.

b) As a consequence of this, the agent negotiates its configuration information to the manager. After getting confirmation from the manager accepting the agent's configuration, the agent device is ready to send measurements. Both devices enter the Operating state. See E.3.2.2 and E.3.2.3 for the corresponding PDU examples.

c) Subsequently, the manager may request the MDS object attributes of the agent by sending a data message with the "Remote Operation Invoke | Get" command. Note that the manager may request the MDS object attributes as soon as the agent enters the Associated state, including the Configuring and Operating substates. As a response, the agent reports its MDS object attributes to the manager using a Data message with the "Remote Operation Response | Get" command. See E.4.1.2 and E.4.1.3 for the corresponding PDU examples.

d) As a next step, the user of the agent device takes a single measurement. The measurement data are transmitted to the manager using a confirmed event report. After having successfully received the measurement data, the manager sends a confirmation to the agent. See E.5.1 and E.5.2 for the corresponding PDU examples.

e) The user ends the measurement session (e.g., by pushing a proper button on the device or just by not using the device for a duration longer than a certain time period). As a consequence, the agent disassociates from the manager by sending an association release request. The manager responds with an association release response. See E.6.1 and E.6.2 for the corresponding PDU examples.

f) When the agent requests to associate to the manager for the next measurement session (e.g., the next day), the result in the manager's response is accepted, as it already knows the agent's configuration from the previous measurement session. Both devices transition directly to the Operating state.

g) Finally, the last two steps shown are similar as in item d) and item e). The user takes a single confirmed measurement followed by releasing the association.

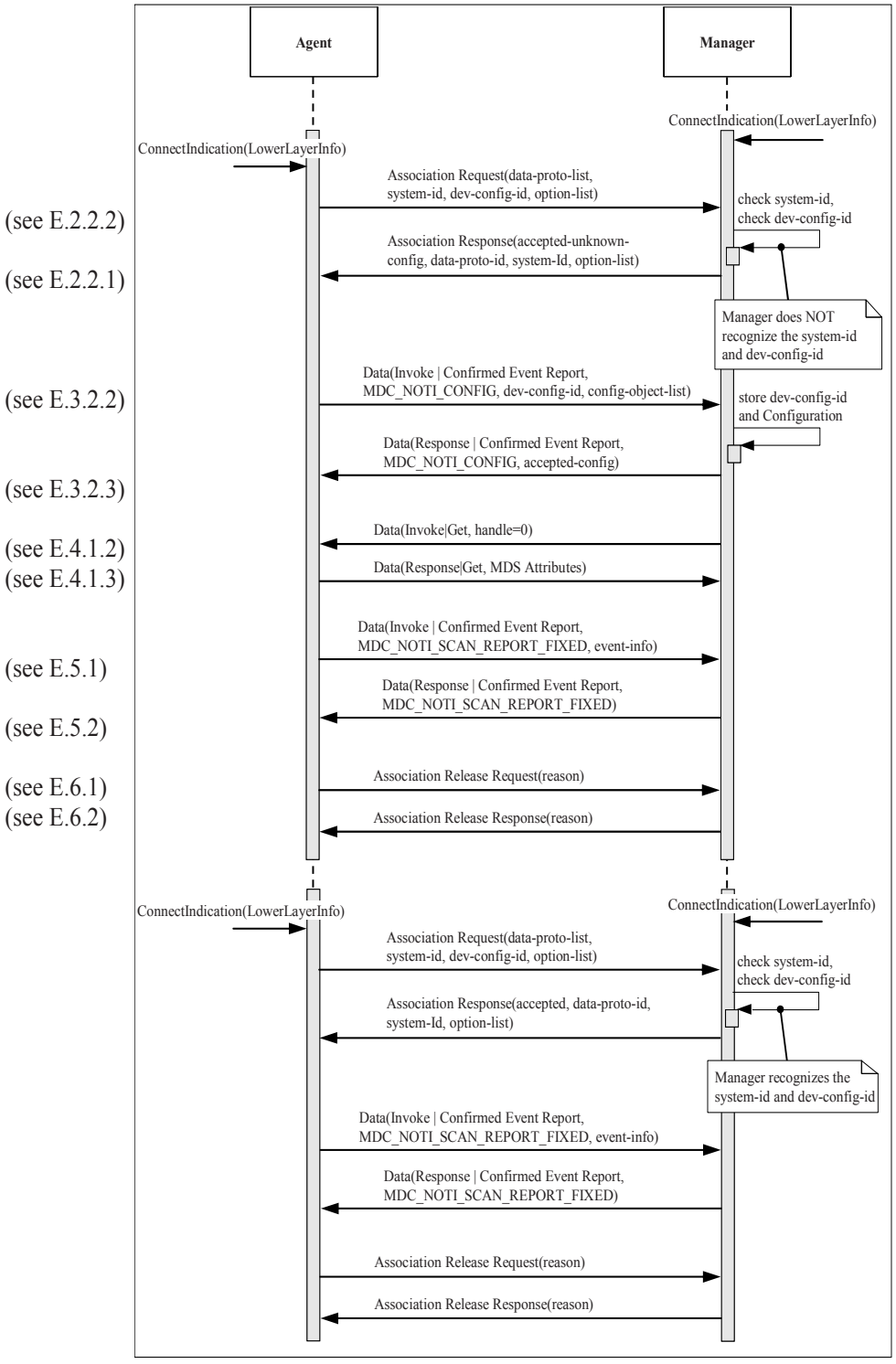

Figure D.1—Sequence diagram for INR monitor example use case

Annex E

(informative)

Protocol data unit examples

E.1 General

This annex shows binary examples of messages exchanged between an INR monitor agent and a manager. Three different scenarios containing the association and configuration information exchanges are presented in E.2 and E.2.3. The first scenario illustrates the case when the agent intends to operate using an extended configuration. The manager does not have the configuration declared by the agent from a prior association. The second illustrates the agent presenting the same extended configuration to the manager, and the manager does have the configuration from the previously transferred configuration exchange. Finally, the agent presents a standard configuration to the manager, and the manager has the configuration because the manager has been preprogrammed with this configuration.

E.2 Association information exchange

E.2.1 General

When the transport connection is established between the manager and the agent, they both enter the Unassociated state. When the agent sends an association request, both manager and agent enter the Associating state.

E.2.2 Extended configuration

E.2.2.1 General

In this exchange, the agent sends an association request intending to use an extended configuration during measurement transfer. However, the manager does not have this configuration.

E.2.2.2 Association request

The INR monitor agent sends the following message to the manager. The agent intends to associate using an extended configuration.

```
0xE2 0x00                   APDU CHOICE Type (AarqApdu)
0x00 0x32                   CHOICE.length = 50
0x80 0x00 0x00 0x00         assoc-version
0x00 0x01 0x00 0x2A         data-proto-list.count = 1 | length = 42
0x50 0x79                   data-proto-id = 20601
0x00 0x26                   data-proto-info length = 38
0x40 0x00 0x00 0x00         protocolVersion set to 11073-20601a
0xA0 0x00                   encoding rules = MDER or PER
0x80 0x00 0x00 0x00         nomenclatureVersion
0x00 0x00 0x00 0x00         functionalUnits – no Test Association capabilities
0x00 0x80 0x00 0x00         systemType = sys-type-agent
0x00 0x08                   system-id length = 8 and value (manufacturer- and device- specific)
0x11 0x22 0x33 0x44 0x55 0x66 0x77 0x88
0x40 0x00                   dev-config-id – extended configuration
```

0x00 0x01	data-req-mode-flags
0x01 0x00	data-req-init-agent-count, data-req-init-manager-count
0x00 0x00 0x00 0x00	optionList.count = 0 | optionList.length = 0

E.2.2.1 Association response

A manager responds to the agent that it can associate but does not have the INR monitor extended configuration (i.e., there is the need for the agent to send its configuration).

0xE3 0x00	APDU CHOICE Type (AareApdu)
0x00 0x2C	CHOICE.length = 44
0x00 0x03	result = accepted-unknown-config
0x50 0x79	data-proto-id = 20601
0x00 0x26	data-proto-info length = 38
0x40 0x00 0x00 0x00	protocolVersion set to 11073-20601a
0x80 0x00	encoding rules = MDER
0x80 0x00 0x00 0x00	nomenclatureVersion
0x00 0x00 0x00 0x00	functionalUnits – normal Association
0x80 0x00 0x00 0x00	systemType = sys-type-manager
0x00 0x08	system-id length = 8 and value (manufacturer- and device- specific)
0x88 0x77 0x66 0x55 0x44 0x33 0x22 0x11	
0x00 0x00	manager's response to config-id is always 0
0x00 0x00	manager's response to data-req-mode-flags is always 0
0x01 0x00	data-req-init-agent-count and data-req-init-manager-count are always 0
0x00 0x00 0x00 0x00	optionList.count = 0 | optionList.length = 0

E.2.3 Previously known extended configuration

E.2.3.1 General

This exchange illustrates a transaction that takes place after a session beginning with an exchange such as E.2.2 has occurred.

E.2.3.2 Association request

The INR monitor agent sends the following message to the manager. The agent intends to associate using an extended configuration.

0xE2 0x00	APDU CHOICE Type (AarqApdu)
0x00 0x32	CHOICE.length = 50
0x80 0x00 0x00 0x00	assoc-version
0x00 0x01 0x00 0x2A	data-proto-list.count = 1 | length = 42
0x50 0x79	data-proto-id = 20601
0x00 0x26	data-proto-info length = 38
0x40 0x00 0x00 0x00	protocolVersion set to 11073-20601a
0xA0 0x00	encoding rules = MDER or PER
0x80 0x00 0x00 0x00	nomenclatureVersion
0x00 0x00 0x00 0x00	functionalUnits – no Test Association capabilities
0x00 0x80 0x00 0x00	systemType = sys-type-agent
0x00 0x08	system-id length = 8 and value (manufacturer- and device- specific)
0x11 0x22 0x33 0x44 0x55 0x66 0x77 0x88	
0x40 0x00	dev-config-id – extended configuration

0x00 0x01	data-req-mode-flags
0x01 0x00	data-req-init-agent-count, data-req-init-manager-count
0x00 0x00 0x00 0x00	optionList.count = 0 | optionList.length = 0

E.2.3.3 Association response

A manager responds to the agent that it can associate with, recognizes, and accepts and has the extended configuration of the INR monitor (i.e., there is no need for the agent to send its configuration).

0xE3 0x00	APDU CHOICE Type (AareApdu)
0x00 0x2C	CHOICE.length = 44
0x00 0x00	result = accepted
0x50 0x79	data-proto-id = 20601
0x00 0x26	data-proto-info length = 38
0x40 0x00 0x00 0x00	protocolVersion set to 11073-20601a
0x80 0x00	encoding rules = MDER
0x80 0x00 0x00 0x00	nomenclatureVersion
0x00 0x00 0x00 0x00	functionalUnits – normal Association
0x80 0x00 0x00 0x00	systemType = sys-type-manager
0x00 0x08	system-id length = 8 and value (manufacturer- and device- specific)
0x88 0x77 0x66 0x55 0x44 0x33 0x22 0x11	
0x00 0x00	manager's response to config-id is always 0
0x00 0x00	manager's response to data-req-mode-flags is always 0
0x00 0x00	data-req-init-agent-count and data-req-init-manager-count are always 0
0x00 0x00 0x00 0x00	optionList.count = 0 | optionList.length = 0

E.2.4 Standard configuration

E.2.4.1 General

This transaction would occur if an agent presents an association request incorporating the dev-config-id corresponding to a standard configuration. The manager has the configuration because it has been programmed with this configuration according to the information presented in this standard.

E.2.4.2 Association request

The INR monitor agent sends the following message to the manager. The agent intends to associate using a standard configuration. The agent is willing to enter into a test association as defined in Clause 9.

0xE2 0x00	APDU CHOICE Type (AarqApdu)
0x00 0x32	CHOICE.length = 50
0x80 0x00 0x00 0x00	assoc-version
0x00 0x01 0x00 0x2A	data-proto-list.count = 1 | length = 42
0x50 0x79	data-proto-id = 20601
0x00 0x26	data-proto-info length = 38
0x40 0x00 0x00 0x00	protocolVersion set to 11073-20601a
0xA0 0x00	encoding rules = MDER or PER
0x80 0x00 0x00 0x00	nomenclature version
0x40 0x00 0x00 0x00	functional units, has test association capabilities
0x00 0x80 0x00 0x00	systemType = sys-type-agent
0x00 0x08	systemID.length
0x11 0x22 0x33 0x44 0x55 0x66 0x77 0x88	System ID

0x07 0x08	dev-config-id – standard configuration
0x00 0x01	data-req-mode-flags
0x01 0x00	data-req-init-agent-count, data-req-init-manager-count
0x00 0x00 0x00 0x00	optionList.count = 0 | optionList.length = 0

E.2.4.3 Association response

A manager responds to the agent that it can associate with, recognizes, and accepts and has the INR monitor standard configuration (i.e., there is no need for the agent to send its configuration). The manager does not start a test association.

0xE3 0x00	APDU CHOICE Type (AareApdu)
0x00 0x2C	CHOICE.length = 42
0x00 0x00	result = accepted
0x50 0x79	data-proto-id = 20601
0x00 0x26	data-proto-info length = 38
0x40 0x00 0x00 0x00	protocolVersion set to 11073-20601a
0x80 0x00	encoding rules = MDER
0x80 0x00 0x00 0x00	nomenclatureVersion
0x00 0x00 0x00 0x00	functionalUnits
0x80 0x00 0x00 0x00	systemType = sys-type-manager
0x00 0x08	system-id length = 8 and value (manufacturer- and device- specific)
0x88 0x77 0x66 0x55 0x44 0x33 0x22 0x11	system-id
0x00 0x00	Manager's response to config-id is always 0
0x00 0x00	Manager's response to data-req-mode-capab is always 0
0x00 0x00	data-req-init-agent-count and data-req-init-manager-count are always 0
0x00 0x00 0x00 0x00	optionList.count = 0 | optionList.length = 0

E.3 Configuration information exchange

E.3.1 General

If the association is not rejected or aborted, the agent and manager transition from the Associating state into one of two states. If the manager's AssociateResult code is accepted, the agent and manager enter the operating state. If the manager's AssociateResult code is accepted-unknown-config, the agent and manager enter the Configuring state.

E.3.2 Extended configuration

E.3.2.1 General

This exchange takes place when the manager returns the AssociateResult code of accepted-unknown-config. The agent presents a description of its configuration corresponding to the dev-config-id it presented in the association request.

E.3.2.2 Remote operation invoke event report configuration

In this example, the INR monitor agent includes the Quick Value and as an extended device. It, therefore, sends the description of its configuration. It does this by sending a confirmed event report of type MDC_NOTI_CONFIG.

0xE7 0x00	APDU CHOICE Type (PrstApdu)
0x00 0x70	CHOICE.length = 112
0x00 0x6E	OCTET STRING.length = 110
0x00 0x02	invoke-id = 2 (start of DataApdu. MDER encoded.)
0x01 0x01	CHOICE(Remote Operation Invoke | Confirmed Event Report)
0x00 0x68	CHOICE.length = 104
0x00 0x00	obj-handle = 0 (MDS object)
0xFF 0xFF 0xFF 0xFF	event-time = 0
0x0D 0x1C	event-type = MDC_NOTI_CONFIG
0x00 0x5E	event-info.length = 94 (start of ConfigReport)
0x40 0x00	config-report-id 16384
0x00 0x02	config-obj-list.count = 2 Measurement objects will be “announced”
0x00 0x58	config-obj-list.length = 88
0x00 0x06	obj-class = MDC_MOC_VMO_METRIC_NU
0x00 0x01	obj-handle = 1 (→ 1st Measurement is INR)
0x00 0x04	attributes.count = 4
0x00 0x24	attributes.length = 36
0x09 0x2F	attribute-id = MDC_ATTR_ID_TYPE
0x00 0x04	attribute-value.length = 4
0x00 0x02 0x72 0x04	MDC_PART_SCADA | MDC_RATIO_INR_COAG
0x0A 0x46	attribute-id = MDC_ATTR_METRIC_SPEC_SMALL
0x00 0x02	attribute-value.length = 2
0xF0 0x40	
0x09 0x96	attribute-id = MDC_ATTR_UNIT_CODE
0x00 0x02	attribute-value.length = 2
0x19 0xD0	MDC_DIM_INR
0x0A 0x55	attribute-id = MDC_ATTR_ATTRIBUTE_VAL_MAP
0x00 0x0C	attribute-value.length = 12
0x00 0x02	AttrValMap.count = 2
0x00 0x08	AttrValMap.length = 8
0x0A 0x4C 0x00 0x02	MDC_ATTR_NU_VAL_OBS_BASIC | value length = 2
0x0A 0x82 0x00 0x08	MDC_ATTR_TIME_STAMP_BO | value length = 8
0x00 0x06	obj-class = MDC_MOC_VMO_METRIC_NU
0x00 0x02	obj-handle = 2 (→ 2nd Measurement is Quick Value)
0x00 0x04	attributes.count = 4
0x00 0x24	attributes.length = 36
0x09 0x2F	attribute-id = MDC_ATTR_ID_TYPE
0x00 0x04	attribute-value.length = 4
0x00 0x02 0x72 0x0C	MDC_PART_SCADA | MDC_QUICK_VALUE_COAG
0x0A 0x46	attribute-id = MDC_ATTR_METRIC_SPEC_SMALL
0x00 0x02	attribute-value.length = 2
0xF0 0x40	
0x09 0x96	attribute-id = MDC_ATTR_UNIT_CODE
0x00 0x02	attribute-value.length = 2
0x19 0xD0	MDC_DIM_PERCENT
0x0A 0x55	attribute-id = MDC_ATTR_ATTRIBUTE_VAL_MAP
0x00 0x0C	attribute-value.length = 12
0x00 0x02	AttrValMap.count = 2
0x00 0x08	AttrValMap.length = 8
0x0A 0x4C 0x00 0x02	MDC_ATTR_NU_VAL_OBS_BASIC | value length = 2
0x0A 0x82 0x00 0x08	MDC_ATTR_TIME_STAMP_BO | value length = 8

E.3.2.3 Remote operation response event report configuration

The manager responds that it can utilize the agent's configuration. The manager does by sending the Confirmed Event Report response with a config-result of accepted-config.

0xE7 0x00	APDU CHOICE Type (PrstApdu)
0x00 0x16	CHOICE.length = 22
0x00 0x14	OCTET STRING.length = 20
0x00 0x02	invoke-id = 0x1235 (mirrored from invocation)
0x02 0x01	CHOICE (Remote Operation Response | Confirmed Event Report)
0x00 0x0E	CHOICE.length = 14
0x00 0x00	obj-handle = 0 (MDS object)
0x00 0x00 0x00 0x00	currentTime = 0
0x0D 0x1C	event-type = MDC_NOTI_CONFIG
0x00 0x04	event-reply-info.length = 4
0x40 0x00	ConfigReportRsp.config-report-id = 0x4000
0x00 0x00	ConfigReportRsp.config-result = accepted-config

E.3.3 Known configuration

E.3.3.1 General

This exchange takes place when the manager returns the AssociateResult code of accepted because the manager had previously received and processed the configuration corresponding to the dev-config-id sent by the agent. In this case, there is no exchange of configuration information, and the manager and agent have moved into the Operating state.

E.3.3.2 Remote operation invoke event report configuration

Since the manager was already aware of the agent's configuration, the Configuring state is skipped, and no event report invocation is generated by the agent.

E.3.3.3 Remote operation response event report configuration

The Configuring state has been skipped. No event report invocation is generated by the agent, so the manager does not generate any response.

E.3.4 Standard configuration

E.3.4.1 General

This exchange takes place when the manager returns the AssociateResult code of accepted because the manager had previously been programmed with the documented standard configuration corresponding to the dev-config-id sent by the agent. In this case, there is no exchange of configuration information, and the manager and agent have moved into the Operating state.

E.3.4.2 Remote operation invoke event report configuration

Since the manager had been programmed with the agent's configuration, the Configuring state is skipped, and no event report invocation is generated by the agent.

E.3.4.3 Remote operation response event report configuration

The Configuring state has been skipped. No event report invocation is generated by the agent, so the manager does not generate any response.

E.4 GET MDS attributes service

E.4.1.1 General

The GET MDS attributes is invoked at any time, when an agent is in Associated state.

E.4.1.2 Get all medical device system attributes request

The manager queries the agent for its MDS Object attributes.

0xE7 0x00	APDU CHOICE Type (PrstApdu)
0x00 0x0E	CHOICE.length = 14
0x00 0x0C	OCTET STRING.length = 12
0x00 0x03	invoke-id = 3 (differentiates this message from any other outstanding, choice is implementation specific)
0x01 0x03	CHOICE (Remote Operation Invoke | Get)
0x00 0x06	CHOICE.length = 6
0x00 0x00	handle = 0 (MDS object)
0x00 0x00	attribute-id-list.count = 0 (all attributes)
0x00 0x00	attribute-id-list.length = 0

E.4.1.3 Get response with all MDS attributes

The INR monitor agent responds to the manager with its attributes. Furthermore, some optional fields are communicated as well.

0xE7 0x00	APDU CHOICE Type (PrstApdu)
0x00 0x6A	CHOICE.length = 106
0x00 0x68	OCTET STRING.length = 104
0x00 0x03	invoke-id = 3 (mirrored from request)
0x02 0x03	CHOICE (Remote Operation Response | Get)
0x00 0x62	CHOICE.length = 98
0x00 0x00	handle = 0 (MDS object)
0x00 0x06	attribute-list.count = 6
0x00 0x5C	attribute-list.length = 92
0x0A 0x5A	attribute id = MDC_ATTR_SYS_TYPE_SPEC_LIST
0x00 0x08	attribute-value.length = 8
0x00 0x01	TypeVerList count = 1
0x00 0x04	TypeVerList.length = 4
0x10 0x16	type = MDC_DEV_SPEC_PROFILE_COAG
0x00 0x01	version = version1 of the specialization
0x09 0x28	attribute id = MDC_ATTR_ID_MODEL
0x00 0x16	attribute-value.length = 22
0x00 0x0A 0x54 0x68 0x65 0x43 0x6F 0x6D 0x70 0x61 0x6E 0x79	string length = 10 | “TheCompany”
0x00 0x08 0x49 0x4E 0x52 0x4D 0x65 0x74	string length = 8 | “INRMeter”

```
0x65 0x72
0x09 0x84                  attribute-id = MDC_ATTR_SYS_ID
0x00 0x0A                  attribute-value.length = 10
0x00 0x08 0x11 0x22 0x33 0x44 0x55 0x66 0x77 0x88  octet string length = 8 | EUI-64
0x0A 0x44                  attribute-id = MDC_ATTR_DEV_CONFIG_ID
0x00 0x02                  attribute-value.length = 2
0x40 0x00                  dev-config-id = 16384 (extended-config-start)
0x09 0x2D                  attribute-id = MDC_ATTR_ID_PROD_SPECN
0x00 0x12                  attribute-value.length = 18
0x00 0x01                              ProductionSpec.count = 1
0x00 0x0E                              ProductionSpec.length = 14
0x00 0x01                              ProductionSpecEntry.spec-type = 1 (serial-number)
0x00 0x00                              ProductionSpecEntry.component-id = 0
0x00 0x08                  string length = 8 | ProductionSpecEntry.prod-spec = "DE124567"
0x44 0x45 0x31 0x32
0x34 0x35 0x36 0x37
0x0A 0x81                  attribute-id = MDC_ATTR_TIME_BO
0x00 0x08                  attribute-value.length = 8
0xC9 0x6B 0x55 0xEC        Base-Offset-Time-Stamp = 2007-02-01T12:05:00.00
0x00 0x00 0x00 0x00        3379254764;0
```

E.5 Data reporting

E.5.1 Confirmed measurement data transmission

The agent sends a spontaneous event report to the manager with measurement observations.

```
0xE7 0x00                  APDU CHOICE Type (PrstApdu)
0x00 0x28                  CHOICE.length = 40
0x00 0x26                  OCTET STRING.length = 38
0x00 0x04                  invoke-id = 4
0x01 0x01                  CHOICE(Remote Operation Invoke | Confirmed Event Report)
0x00 0x20                  CHOICE.length = 32
0x00 0x00                  obj-handle = 0 (MDS object)
0xFF 0xFF 0xFF 0xFF        event-time = 0xFFFFFFFF
0x0D 0x1D                  event-type = MDC_NOTI_SCAN_REPORT_FIXED
0x00 0x16                  event-info.length = 22
0xF0 0x00                  ScanReportInfoFixed.data-req-id = 0xF000
0x00 0x01                  ScanReportInfoFixed.scan-report-no = 1
0x00 0x01                  ScanReportInfoFixed.obs-scan-fixed.count = 1
0x00 0x0E                  ScanReportInfoFixed.obs-scan-fixed.length = 14
0x00 0x01                  ScanReportInfoFixed.obs-scan-fixed.value[0].obj-handle = 1
0x00 0x0A                  ScanReportInfoFixed.obs-scan-fixed.value[0]. obs-val-data.length = 10
0xE1 0x2C                  Basic-Nu-Observed-Value = 3.0 INR Units
0xCA 0x98 0xB9 0x88        Base-Offset-Time-Stamp = 2007-09-17T08:30:00.00
0x00 0x00 0x00 0x00        3399006600;0
```

E.5.2 Response to confirmed measurement data transmission

The manager confirms receipt of the agent's event report.

```
0xE7 0x00                  APDU CHOICE Type (PrstApdu)
```

0x00 0x12	CHOICE.length = 18
0x00 0x10	OCTET STRING.length = 16
0x00 0x04	invoke-id = 4 (mirrored from invocation)
0x02 0x01	CHOICE(Remote Operation Response | Confirmed Event Report)
0x00 0x0A	CHOICE.length = 10
0x00 0x00	obj-handle = 0 (MDS object)
0x00 0x00 0x00 0x00	currentTime = 0
0x0D 0x1D	event-type = MDC_NOTI_SCAN_REPORT_FIXED
0x00 0x00	event-reply-info.length = 0

E.6 Disassociation

E.6.1 Association release request

The INR monitor agent sends the following message to the manager.

0xE4 0x00	APDU CHOICE Type (RlrqApdu)
0x00 0x02	CHOICE.length = 2
0x00 0x00	reason = normal

E.6.2 Association release response

A manager responds to the agent that it can release association.

0xE5 0x00	APDU CHOICE Type (RlreApdu)
0x00 0x02	CHOICE.length = 2
0x00 0x00	reason = normal

Annex F
(informative)

IEEE list of participants

Participants

At the time this standard was submitted to the IEEE-SA Standards Board for approval, the Personal Health Device Working Group had the following membership:

Douglas P. Bogia, *Chair*
Malcom Clarke, *Vice Chair*

Karsten Aalders
Charles R. Abbruscato
Nabil Abujbara
Maher Abuzaid
Jon Adams
Manfred Aigner
Jorge Alberola
Murtaza Ali
Prasad Alva
Rolf Ambuehl
David Aparisi
Lawrence Arne
Serafin Arroyo
Muhammad Asim
Merat Bagha
Doug Baird
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Sunlee Bang
M. Jonathan Barkley
Gilberto Barrón
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Abstract: ISO/IEEE 11073-10418:2014 establishes a normative definition of communication between personal telehealth International Normalized Ratio (INR) 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. Work done in other ISO/IEEE 11073 standards is leveraged, including existing terminology, information profiles, application profile standards and transport standards. The use of specific term codes, formats and behaviours in telehealth environments restricting optionality in base frameworks in favour of interoperability is specified. A common core of functionality of INR devices is defined in ISO/IEEE 11073-10418:2014. In the context of personal health devices, the measurement of the prothrombin time (PT) that is used to assess the level of anticoagulant therapy and its presentation as the International Normalized Ratio compared to the prothrombin time of normal blood plasma is referred to in INR monitoring. Applications of the INR monitor include the management of the therapeutic level of anticoagulant used in the treatment of a variety of conditions. The data modeling and its transport shim layer according to ISO/IEEE 11073-20601:2010 are provided by ISO/IEEE 11073:10418:2014, and the measurement method is not specified.

Keywords: IEEE 11073-10418, International Normalized Ratio (INR) monitor, medical device communication, personal health devices

ICS 35.240.80
ISBN (PDF) 978-0-7381-6704-6; ISBN (Print) 978-0-7381-6705-3
Price based on 60 pages

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