

Health informatics—Personal health device communication

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

IEEE Engineering in Medicine and Biology Society

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IEEE 11073™ Standards Committee

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USA

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Sponsor

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of the

IEEE Engineering in Medicine and Biology Society

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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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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

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1. Overview

1.1 Scope

The scope of this standard is to establish a normative definition of communication between personal telehealth 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™-2010¹ 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.

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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.

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

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.

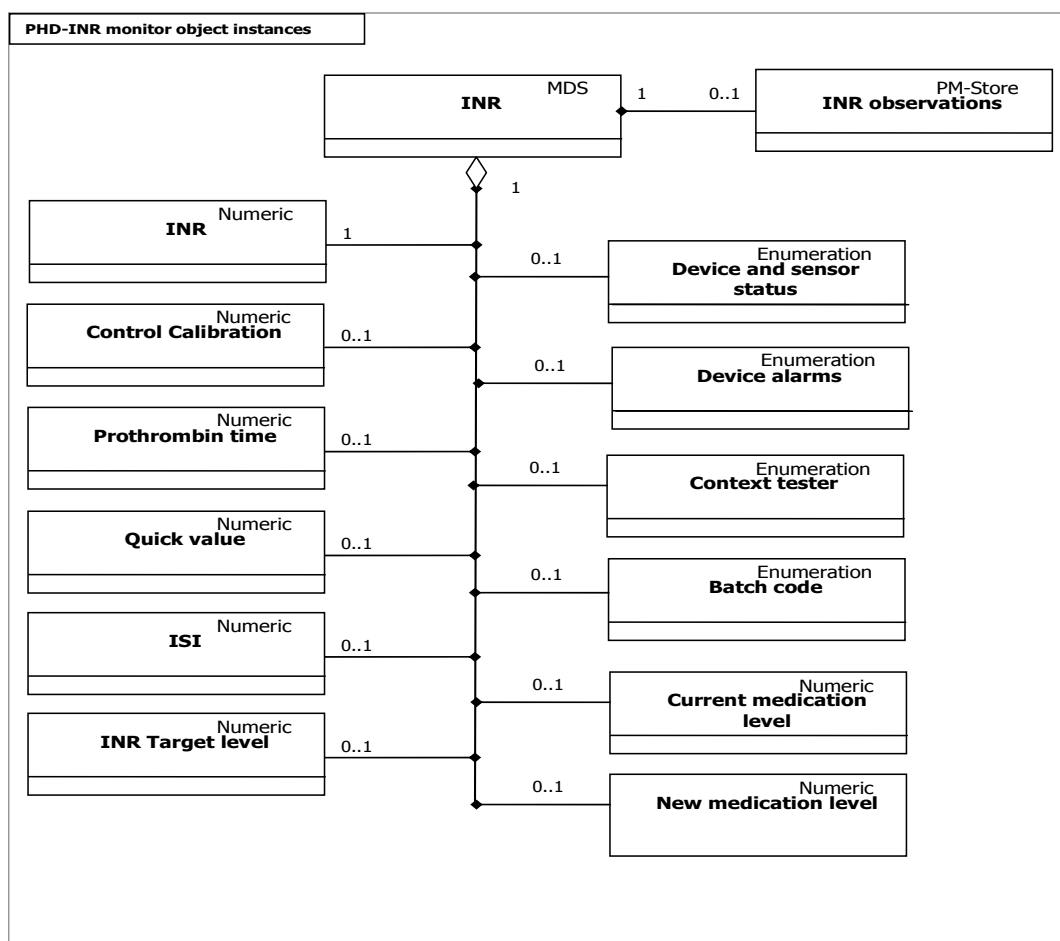


Figure 1—INR monitor—domain information model