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Health informatics — Personal health device communication —

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

Informatique de santé — Communication entre dispositifs de santé personnels —

Partie 10406: Spécialisation des dispositifs — Électrocardiographe de base (ECG) (ECG 1 à 3)

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Contents

Foreword

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ISO/IEEE 11073-10406 was prepared by the IEEE 11073 Standards Comittee of the IEEE Engineering in Medicine and Biology Society (as IEEE Std 11073-10406-2011). It was adopted by Technical Committee ISO/TC 215, *Health informatics*, in parallel with its approval by the ISO member bodies, under the "fast-track procedure" defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE. IEEE is responsible for the maintenance of this document with participation and input from ISO member bodies.

ISO/IEEE 11073 consists of the following parts, under the general title *Health informatics — Personal health device communication* (text in parentheses gives a variant of subtitle):

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

— *Part 10201: (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 10420: Device specialization — Body composition analyzer*

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

— *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*

— *Part 92001: (Medical waveform format) — Encoding rules [Technical Specification]*

Introduction

This introduction is not part of IEEE Std 11073-10406-2011, Health informatics—Personal health device communication—Part 10406: Device specialization—Basic electrocardiograph (ECG) (1- to 3-lead ECG).

Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of the communication between personal basic electrocardiograph (ECG) 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 IEEE 11073-20601 information models. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for personal telehealth basic ECG (1- to 3-lead ECG) devices. Monitoring ECG devices are distinguished from diagnostic ECG equipment with respect to including support for wearable ECG devices, limiting the number of leads supported by the equipment to three, and not requiring the capability of annotating or analyzing the detected electrical activity to determine known cardiac phenomena. This standard is consistent with the base framework and allows multifunction implementations by following multiple device specializations (e.g., ECG and respiration rate).

Health informatics — Personal health device communication —

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

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1. Overview

1.1 Scope

Within the context of the ISO/IEEE 11073 family of standards for device communication, this standard establishes a normative definition of the communication between personal basic electrocardiograph (ECG) 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 IEEE Std 11073-20601 information models. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. This standard defines a common core of communication functionality for personal telehealth basic ECG (1- to 3-lead ECG) devices. Monitoring ECG devices are distinguished from diagnostic ECG equipment with respect to including support for wearable ECG devices, limiting the number of leads supported by the equipment to three, and not requiring the capability of annotating or analyzing the detected electrical activity to determine known cardiac phenomena. This standard is consistent with the base framework and allows multifunction implementations by following multiple device specializations (e.g., ECG and respiration rate).

1.2 Purpose

This standard addresses a need for an openly defined, independent standard for controlling information exchange to and from personal health devices and managers (e.g., cell phones, personal computers, personal health appliances, and set top boxes). Interoperability is key to growing the potential market for these devices and enabling people to be better informed participants in the management of their health.

1.3 Context

See IEEE Std 11073-20601a-2010[1] for an overview of the environment within which this standard is written.

This standard defines the device specialization for the basic ECG (1- to 3-lead ECG), being a specific agent type, and it provides a description of the device concepts, its capabilities, and its implementation according to this standard.

This standard is based on IEEE Std 11073-20601a™-2010 and ISO/IEEE 11073-20601:2010, which in turn draw information from both ISO/IEEE 11073-10201:2004 [B7][2] and ISO/IEEE 11073-20101:2004 [B8]. The medical device encoding rules (MDERs) used within this standard are fully described in ISO/IEEE 11073-20601:2010.

This standard reproduces relevant portions of the nomenclature found in ISO/IEEE 11073-10101:2004 0 and adds new nomenclature codes for the purposes of this standard. Among this standard, ISO/IEEE 11073-20601:2010, 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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[1] Information on references can be found in Clause 2.
[2] The numbers in brackets correspond to those of the bibliography in Annex A.
[3] Notes in text, tables, and figures are given for information only and do not contain requirements needed to implement the standard.
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[6] 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/).

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]

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

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

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

3.1.4 electrode: An electrical sensor in contact with a specified part of the body. Two or more electrodes are used to detect heart action voltage. *See*: **lead**.

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

3.1.6 lead: Commonly refers to two different things: It may be used to refer to the combination of an electrode and associated lead wire, used for a certain ECG recording. Alternatively, it may be used to refer to the signal obtained by tracing the voltage between two electrodes or linear combinations thereof. The latter definition is used throughout this standard.

3.1.7 lead wire: A cable connected between an electrode and the agent device.

3.1.8 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.

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

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

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

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

3.2 Acronyms and abbreviations

APDU   application protocol data unit
ASN.1   Abstract Syntax Notation One
DIM   domain information model
ECG   electrocardiogram or electrocardiograph
EKG   elektrokardiogramm (German)
EUI-64   extended unique identifier (64 bits)
ICS   implementation conformance statements

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

MDC	medical device communication
MDER	medical device encoding rules
MDS	medical device system
MOC	managed object class
PDU	protocol data unit
PHD	personal health device
RT-SA	real-time sample array
VMO	virtual medical object
VMS	virtual medical system

4. Introduction to ISO/IEEE 11073 personal health devices

4.1 General

This standard and the remainder of the series of ISO/IEEE 11073 personal health device (PHD) standards fit in the larger context of the ISO/IEEE 11073 series of standards. The full suite of standards enables agents to interconnect and interoperate with managers and with computerized 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 basic ECG (1- to 3-lead ECG) device. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 PHD basic ECG (1- to 3-lead ECG) 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 the 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 0 base standards with respect to electrical and mechanical safety and any device-specific standard as might be defined in the IEC 60601-2 [B2] series of standards. Software aspects may apply through standards such as IEC 62304:2006/EN 62304:2006 [B3]. Devices that comply with this standard implement higher layers of network software and utilize lower layers as appropriate to the application. The requirements on performance of such applications and conformance are defined elsewhere and are outside the scope of this standard. Moreover, the use of any medical equipment is subject to risk assessment and risk management appropriate to the application. Some relevant examples are ISO 14971:2007 [B5] and IEC 80001-1:2010 [B4]. The requirements of such risk assessment and risk management and conformance are outside the scope of this standard.

5. Basic ECG (1- to 3-lead ECG) device concepts and modalities

5.1 General

This clause presents the general concepts of basic ECG (1- to 3-lead ECG) devices. In general, an ECG device with associated lead wires and electrodes measures the electrical activity of the heart. More precisely, it measures the electrical potential differences between electrodes placed on the person's body, reflecting the sum of the electrical activities of muscle fibers. These electrical activities are related to the myocardial muscle but also include artifacts caused by electrical activities of other muscle fibers after movement. In the context of personal health devices in this family of standards, a basic ECG (1- to 3-lead ECG) is used for the purpose of acquiring and recording 1 to 3 channel (leads) electrocardiographic waveforms or analyzing the acquired signals to measure heart rate.

The electrical potential is measured by means of a system of conducting wires attached to a person using electrodes. The electrodes are placed on specific locations on the surface of the person's body. There are different lead measurement systems for placing the electrodes on the person's body.

5.2 ECG waveform

ECG waveforms represent a continuous stream of measured electrical potential differences within a certain time period. ECG waveforms are typically used for cardiac rhythm monitoring.

5.3 R-R interval

Figure 1 illustrates the basic ECG signal and specific waveforms that may occur, for example, during atrial depolarization (P wave), ventricular depolarization (QRS complex), and ventricular repolarization (ST-T wave). The R-R interval (interbeat interval) is an instantaneous measurement defined as the time between the maximums of two consecutive R-waves (early ventricular depolarization), and it is typically indicated in milliseconds or an internal oscillator count. The latter is used in order to simplify implementations or to support higher accuracy by avoiding round off errors and is referred to as ticks and defined as ticks per second in this standard. Conceptually the R-R interval measurement is implemented by means of a detector that registers the time instant of each individual R peak and subsequently calculates the interval in between them.
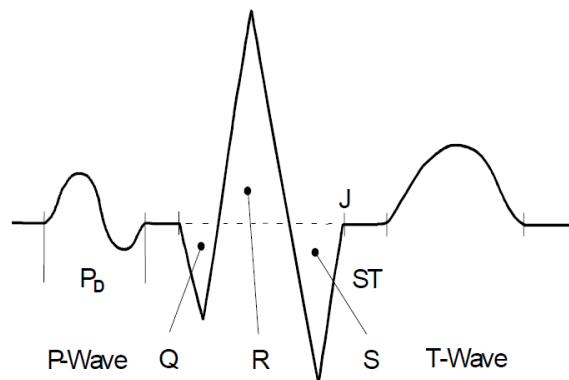
Figure 1—Basic form of ECG signal

5.4 Heart rate

Heart rate is defined as the number of heartbeats per unit of time. Typically, this value is quoted as beats per minute, although often a period less than 1 min is used to determine the number of beats that have occurred, and the value is normalized. A heart rate measurement based on a single beat interval is termed the instantaneous heart rate. The instantaneous heart rate is defined as the inverse of a single R-R value, subject to a proper normalization factor accounting for the conversion from beats per millisecond to beats per minute. The instantaneous heart rate is often fluctuating and is therefore filtered (averaged) reducing higher frequency content for the purposes of display.

6. Basic ECG (1- to 3-lead ECG) domain information model

6.1 Overview

This clause describes the domain information model of the basic ECG (1- to 3-lead ECG).

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 metric object instance diagram of the basic ECG (1- to 3-lead ECG) domain information model, defined for the purposes of this standard, is shown in Figure 2.

The objects of the DIM, as shown in Figure 2, are described in 6.6 through 6.11. This includes the medical device system (MDS) object (see 6.6), the numeric objects (see 6.7), the RT-SA objects (see 6.8), the enumeration objects (see 6.9), the PM-store objects (see 6.10), and the scanner objects (see 6.11). See 6.13 for rules for extending the basic ECG (1- to 3-lead ECG) information model beyond elements as described in this standard. Each clause that describes an object of the basic ECG (1- to 3-lead ECG) 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.
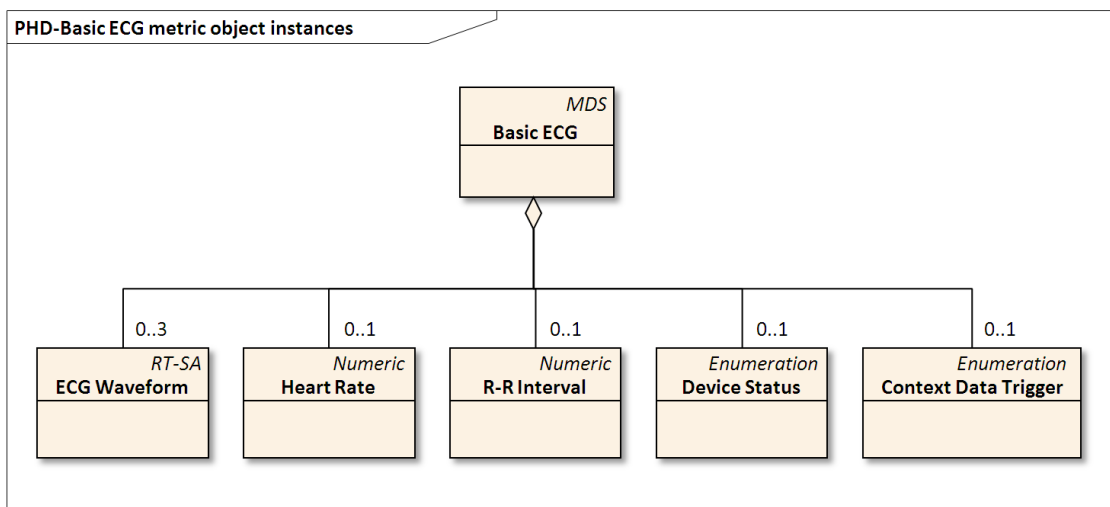
Figure 2—Basic ECG (1- to 3-lead ECG)—domain information model

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. The DIM of the standard configuration defined in this standard is described in 6.5.3.

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 Profiles

6.5.1 General

A profile further constrains the objects, services, and communication model of a specialization. By profiling the device specialization, the standard provides more guidance on the specific mandatory objects that shall be implemented, the objects that are optional, and the objects that are not required. This standard defines two profiles, the simple ECG profile (see 6.5.2) and the heart rate
profile (see 6.5.3). A basic ECG (1- to 3-lead ECG) device shall implement at least one of these two profiles.

6.5.2 Simple ECG profile

The metric object instance diagram of the simple ECG profile domain information model is shown in Figure 3. A basic ECG (1- to 3-lead ECG) device implementing the simple ECG profile shall implement 1 to 3 ECG waveform RT-SA objects. For the simple ECG profile, currently no standard configuration is defined.
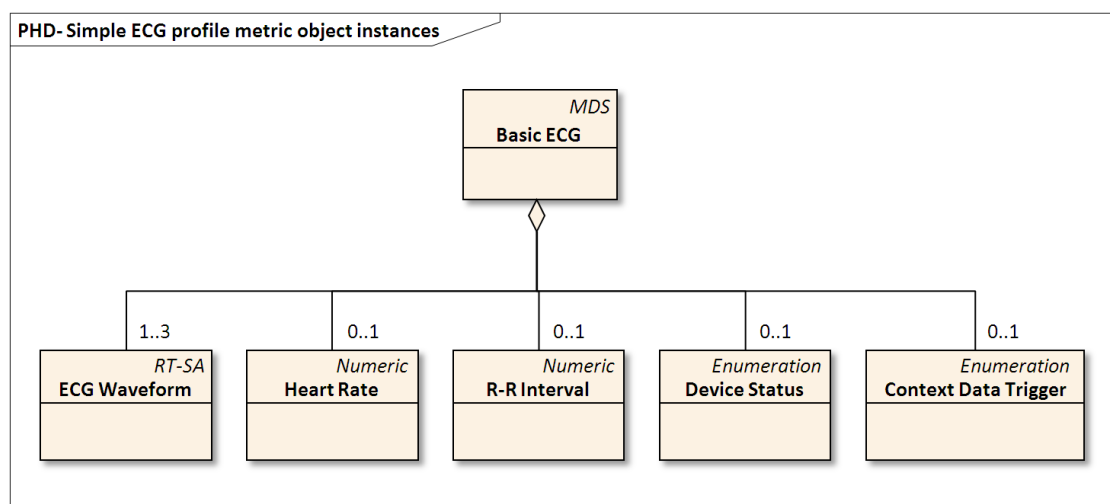
Figure 3—Simple ECG profile—metric objects

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6.5.3 Heart rate profile

The metric object instance diagram of the heart rate profile domain information model is shown in Figure 4. The heart rate numeric object shall be supported by a basic ECG (1- to 3-lead ECG) device implementing the heart rate profile.
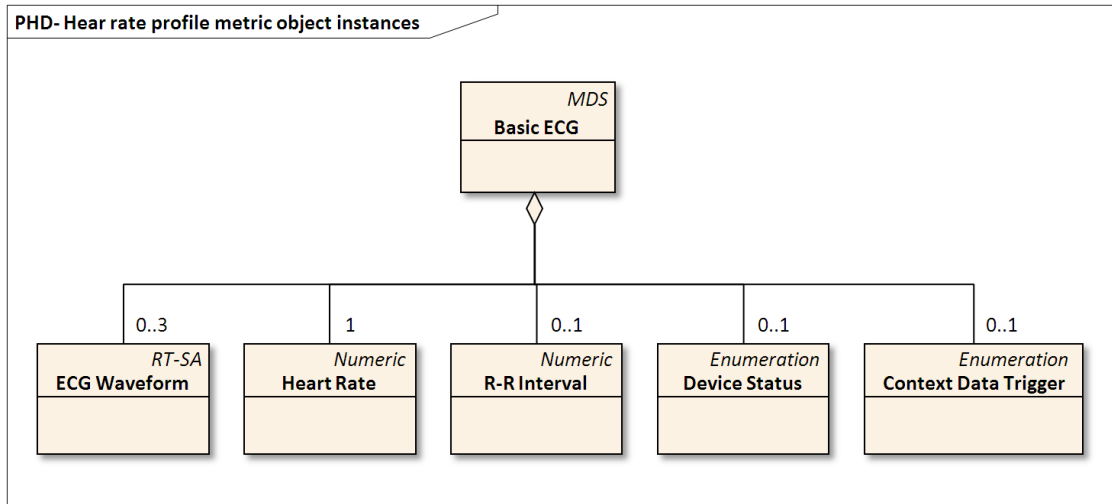
Figure 4—Heart rate profile—metric objects

If and only if an agent supports the heart rate profile, it shall support the standard configuration with Dev-Configuration-ID value 0x258. The DIM for this standard configuration contains a single heart rate numeric object. The corresponding metric object instance diagram is shown in Figure 5.
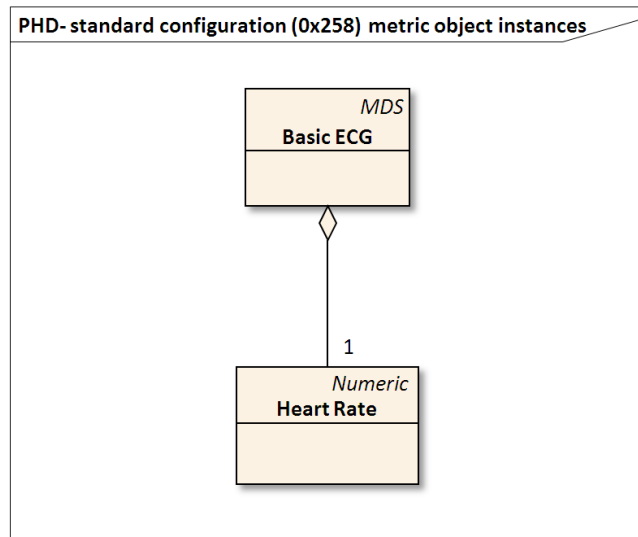
Figure 5—Heart rate profile—standard configuration (0x258)—metric objects

6.6 Medical device system object

6.6.1 MDS object attributes

Table 1 summarizes the attributes of the basic ECG (1- to 3-lead ECG) 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.	NR
System-Type-Spec-List	Specialization value: {MDC_DEV_SPEC_PROFILE_ECG, 1} and Profile value: {MDC_DEV_SUB_SPEC_PROFILE_ECG, 1} or {MDC_DEV_SUB_SPEC_PROFILE_HR, 1}	M
System-Model	{"Manufacturer","Model"}	M
System-Id	Extended unique identifier (64-bits) (EUI-64)	M
Dev-Configuration-Id	Standard config: 0x0258 (600) 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.	C
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
Tick-Resolution	See 6.6.2.	C

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.

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. For a basic ECG (1- to 3-lead ECG) agent, a specialization value of MDC_DEV_SPEC_PROFILE_ECG shall be included in the System-Type-Spec-List attribute as shown in Table 1. Additionally, the value(s) for the supported profile(s) shall be included in the System-Type-Spec-List attribute. The profile value for a basic ECG (1- to 3-lead ECG) agent supporting the simple ECG profile shall be set to MDC_DEV_SUB_SPEC_PROFILE_ECG. The profile value for a basic ECG (1- to 3-lead ECG) agent supporting the heart rate profile shall be set to MDC_DEV_SUB_SPEC_PROFILE_HR.

The Dev-Configuration-Id attribute holds a locally unique 16-bit identifier that identifies the device configuration. For a basic ECG (1- to 3-lead ECG) 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.

6.6.2 Tick-Resolution attribute

The Tick-Resolution attribute specifies the resolution of the agent's internal oscillator and provides the context information when the corresponding Unit-Code attribute is equal to MDC_DIM_TICK, which is for optional use when measuring the R-R interval (see 6.7.3). Table 2 defines the Tick-Resolution attribute.

Table 2—Basic ECG (1- to 3-lead ECG) Tick-Resolution attribute

Attribute name	Attribute ID	Attribute type	Remark	Qualifiers
Tick-Resolution	MDC_ATTR_TICK_RES	FLOAT-Type	This attribute defines the resolution for the agent's internal oscillator (i.e., it specifies the number of ticks per second). If the agent implements the R-R interval object (see 6.6.3) and uses MDC_DIM_TICK for the corresponding Unit-Code attribute, the Tick-Resolution attribute shall be implemented.	Conditional Static

NOTE—The number of ticks per second is not necessarily an integer value but can be fractional.

6.6.3 MDS object methods

Table 3 defines the methods (actions) of the MDS object. These methods are invoked using the Action service. In Table 3, 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 3—MDS object methods

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

Set-Time

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

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

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 basic ECG (1- to 3-lead ECG) 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 3.

6.6.4 MDS object events

Table 4 defines the events that can be sent by the basic ECG (1- to 3-lead ECG) MDS object.

Table 4—Basic ECG (1- to 3-lead ECG) 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	ConfigReport Rsp
	MDS-Dynamic-Data-Update-Var	Confirmed or unconfirmed	MDC_NOTI_SCAN_REPORT_VAR	ScanReportInfoVar	—
	MDS-Dynamic-Data-Update-Fixed	Confirmed or unconfirmed	MDC_NOTI_SCAN_REPORT_FIXED	ScanReportInfoFixed	—
	MDS-Dynamic-Data-Update-MP-Var	Confirmed or unconfirmed	MDC_NOTI_SCAN_REPORT_MP_VAR	ScanReportInfoMPVar	—
	MDS-Dynamic-Data-Update-MP-Fixed	Confirmed or unconfirmed	MDC_NOTI_SCAN_REPORT_MP_FIXED	ScanReportInfoMPFixed	—

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— **MDS-Configuration-Event:**
This event is sent by the basic ECG (1- to 3-lead ECG) agent during the configuring procedure if the manager does not already know the basic ECG (1- to 3-lead ECG) agent's configuration from past associations or because the manager has not been implemented to recognize the configuration according to the basic ECG (1- to 3-lead ECG) device specialization. The event provides static information about the supported measurement capabilities of the basic ECG (1- to 3-lead ECG) agent.

— **MDS-Dynamic-Data-Update-Var:**
This event provides dynamic measurement data from the basic ECG (1- to 3-lead ECG) agent for the numeric and enumeration objects. 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 basic ECG (1- to 3-lead ECG) agent for the numeric and enumeration objects. These data are reported in the fixed format defined by the Attribute-Value-Map attribute of the objects. 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 above.

6.6.5 Other MDS services

6.6.5.1 GET service

A basic ECG (1- to 3-lead ECG) 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 basic ECG (1- to 3-lead ECG) 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 basic ECG (1- to 3-lead ECG) 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 basic ECG (1- to 3-lead ECG) 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 5 for a summary of the GET service including some message fields.

Table 5—Basic ECG (1- to 3-lead ECG) 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.

6.6.5.2 SET service

The basic ECG (1- to 3-lead ECG) specialization does not require an implementation to support the MDS object SET service.

6.7 Numeric objects

6.7.1 General

The basic ECG (1- to 3-lead ECG) DIM for metric objects (see Figure 2) contains two numeric objects for heart rate and R-R interval. The heart rate numeric object is described in 6.7.2. The R-R interval numeric object is described in 6.7.3.

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 6.6.4) prior to reporting any of the dependent values.

6.7.2 Heart rate

Table 6 summarizes the attributes of the heart rate numeric object. If the Dev-Configuration-Id value of the agent is set to 0x258, the heart rate numeric object shall be implemented. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU.

Table 6—Heart rate numeric object attributes

Attribute name	Extended configuration		Standard configuration (Dev-Configuration-Id = 0x0258)	
	Value	Qual.	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M	1	M
Type	{MDC_PART_SCADA ,| MDC_ECG_HEART_RATE} or {MDC_PART_PHD_DIM ,| MDC_ECG_HEART_RATE_INSTANT}	M	{MDC_PART_SCADA |, MDC_ECG_HEART_RATE}	M
Supplemental-Types	See IEEE Std 11073-20601a-2010.	NR	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010.	NR
Metric-Spec-Small	See IEEE Std 11073-20601a-2010 and following text.	M	mss-avail-stored-data, mss-acc-agent-initiated	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.	O	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010.	O
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

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	Extended configuration		Standard configuration (Dev-Configuration-Id = 0x0258)	
Unit-Code	MDC_DIM_BEAT_PER_MIN	M	MDC_DIM_BEAT_PER_MIN	M
Attribute-Value-Map	See IEEE Std 11073-20601a-2010.	C	MDC_ATTR_NU_VAL_OBS_BASIC, then MDC_ATTR_TIME_STAMP_ABS	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.	NR
Base-Offset-Time-Stamp	See IEEE Std 11073-20601a-2010.	C	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010.	NR
Relative-Time-Stamp	See IEEE Std 11073-20601a-2010.	C	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
HiRes-Time-Stamp	See IEEE Std 11073-20601a-2010.	C	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010.	NR
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	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010.	NR
Compound-Simple-Nu-Observed-Value	See /IEEE Std 11073-20601a-2010.	C	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010	NR
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	C	Attribute not initially present. 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	NR
Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	C	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010.	NR
Compound-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	C	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010.	NR
Accuracy	See IEEE Std 11073-20601a-2010.	NR	Attribute not initially present. If present follow IEEE Std 11073-20601a-2010.	NR

NOTE 1—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

NOTE 2—It is not specified from which lead the heart rate measurement is derived.

For a basic ECG (1- to 3-lead ECG) 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 as indicated in Table 6.

If the heart rate measurement represents instantaneous heart rate, the Type attribute shall be set to {MDC_PART_PHD_DIM | MDC_ECG_HEART_RATE_INSTANT}. Otherwise, the heart rate measurement represents an average value and the Type attribute shall be set to {MDC_PART_SCADA | MDC_ECG_HEART_RATE_INSTANT}, with the averaging function not further specified.

The Metric-Spec-Small attribute is used to define the modality of a particular heart rate measurement. If the heart rate represents a beat-to-beat measurement, then the mss-msmt-btb-metric as well as the mss-msmt-aperiodic bits shall be set for the Metric-Spec-Small attribute.

The heart rate 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.

6.7.3 R-R interval

Table 7 summarizes the attributes of the R-R interval numeric object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU.

Table 7—R-R interval numeric object attributes

Attribute name	Extended configuration	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M
Type	{MDC_PART_SCADA , MDC_ECG_TIME_PD_RR_GL }	M
Supplemental-Types	See IEEE Std 11073-20601a-2010.	NR
Metric-Spec-Small	See IEEE Std 11073-20601a-2010 and following text.	M
Metric-Structure-Small	See IEEE Std 11073-20601a-2010.	NR
Measurement-Status	See IEEE Std 11073-20601a-2010.	O
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	MDC_DIM_MILLI_SEC or MDC_DIM_TICK	M
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.	C
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
Simple-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	C
Compound-Simple-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	C
Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	C
Compound-Basic-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	C
Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	C
Compound-Nu-Observed-Value	See IEEE Std 11073-20601a-2010.	C
Accuracy	See IEEE Std 11073-20601a-2010.	NR

NOTE 1—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

NOTE 2—It is not further specified from which lead the R-R interval measurement is derived.

As R-R interval represents an instantaneous measurement available on a beat-to-beat basis; the mss-msmt-btb-metric as well as the mss-msmt-aperiodic bits shall be set for the Metric-Spec-Small attribute.

If MDC_DIM_TICK is used for Unit-Code, the resolution of the agent's tick for measuring the R-R interval is defined by the Tick-Resolution attribute of the MDS object (see Table 1).

The R-R interval 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.

6.8 Real-time sample array (RT-SA) objects

6.8.1 General

The basic ECG (1- to 3-lead ECG) DIM for metric objects (see Figure 2) contains an RT-SA object for ECG waveform data.

6.8.2 ECG waveform

ECG waveforms are transmitted as a series of samples with each waveform represented as a separate object.

Table 8 summarizes the attributes of the ECG waveform RT-SA object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_SA_RT.

Table 8—ECG waveform RT-SA object attributes

Attribute name	Extended configuration	
	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M
Type	{MDC_PART_SCADA, see Table 9 for supported lead measurement types}	M
Supplemental-Types	See IEEE Std 11073-20601a-2010.	NR
Metric-Spec-Small	0x0000 (no bit set)	M
Measurement-Status	See IEEE Std 11073-20601a-2010.	O
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	MDC_DIM_MILLI_VOLT	M
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.	C
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
Sample-Period	See IEEE Std 11073-20601a-2010.	M
Simple-Sa-Observed-Value	See IEEE Std 11073-20601a-2010.	M
Scale-and-Range-Specification	See IEEE Std 11073-20601a-2010.	M
Sa-Specification	See IEEE Std 11073-20601a-2010.	M

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

For the Type attribute, one of the nomenclature codes as listed in Table 9 shall be used.

Table 9—ECG lead measurement types

Type	Value	Lead
MDC_ECG_ELEC_POTL	256	Unspecified Lead
MDC_ECG_ELEC_POTL_I	257	Lead I
MDC_ECG_ELEC_POTL_II	258	Lead II
MDC_ECG_ELEC_POTL_III	317	Lead III
MDC_ECG_ELEC_POTL_AVR	318	Augmented voltage right (aVR)
MDC_ECG_ELEC_POTL_AVL	319	Augmented voltage left (aVL)
MDC_ECG_ELEC_POTL_AVF	320	Augmented voltage foot (aVF)
MDC_ECG_ELEC_POTL_V1	259	Lead V1
MDC_ECG_ELEC_POTL_V2	260	Lead V2
MDC_ECG_ELEC_POTL_V3	261	Lead V3
MDC_ECG_ELEC_POTL_V4	262	Lead V4
MDC_ECG_ELEC_POTL_V5	263	Lead V5
MDC_ECG_ELEC_POTL_V6	264	Lead V6

The ECG waveform data shall be made available only through a scanner object. Consequently, the mss-acc-manager bit and the mss-acc-agent-initiated bit in the Metric-Spec-Small attribute shall be zero (see Table 8).

6.9 Enumeration objects

6.9.1 General

The basic ECG (1- to 3-lead ECG) DIM contains two enumeration objects. The device status numeric object is described in 6.9.2. The context data trigger enumeration object is described in 6.9.3.

6.9.2 Device status

The device status enumeration object informs the user of device-related events, such as lead wire loss or lead signal loss. The status of each aspect is reported by a specific status bit. The nomenclature code to identify the enumeration object class is MDC_MOC_VMO_METRIC_ENUM. Refer to Table 10 for the set of attributes of this object.

19

Table 10 —Device status enumeration object attributes

Attribute name	Extended configuration	
	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M
Type	{MDC_PART_PHD_DM, MDC_ECG_DEV_STAT}	M
Supplemental-Types	See IEEE Std 11073-20601a-2010.	NR
Metric-Spec-Small	See IEEE Std 11073-20601a-2010.	M
Metric-Structure-Small	See IEEE Std 11073-20601a-2010.	NR
Measurement-Status	See IEEE Std 11073-20601a-2010.	O
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.	C
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.	NR
Enum-Observed-Value-Simple-Bit-Str	See IEEE Std 11073-20601a-2010.	NR
Enum-Observed-Value-Basic-Bit-Str	See IEEE Std 11073-20601a-2010 and the following text.	M
Enum-Observed-Value-Simple-Str	See IEEE Std 11073-20601a-2010.	NR
Enum-Observed-Value	See IEEE Std 11073-20601a-2010.	NR
Enum-Observed-Value-Partition	See IEEE Std 11073-20601a-2010.	NR

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

Because these are essentially event flags, the Unit-Code attribute is not appropriate for this object. Similarly, the Source-Handle-Reference is inappropriate as this object monitors the status of the equipment.

For explicit expression of the existence of a device-related event, the appropriate bits in the Enum-Observed-Value-Basic-Bit-Str attribute shall be set as defined in Table 11. If a manager supports the interpretation of this object, it shall be able to interpret the entire set of presented conditions defined in Table 11. An agent is not required to implement all the features specified in Table 11. Anytime the status changes for any monitored condition, the agent shall report on all monitored 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 11 —Mapping of device, lead, and signal status to object Bit-Str attribute

Device or lead condition	BasicECGDevStat mnemonic
Agent reports loss of lead wire or electrode connection (lead unspecified)	leadwire-loss
Agent reports loss of lead signal (lead unspecified)	leadsignal-loss
Agent reports loss of lead wire or electrode connection (first lead)	leadwire-loss-first-lead
Agent reports loss of lead signal (first lead)	leadsignal-loss-first-lead
Agent reports loss of lead wire or electrode connection (second lead)	leadwire-loss-second-lead
Agent reports loss of lead signal (second lead)	leadsignal-loss-second-lead
Agent reports loss of lead wire or electrode connection (third lead)	leadwire-loss-third-lead
Agent reports loss of lead signal (third lead)	leadsignal-loss-third-lead

In Table 11, unspecified lead refers to an event related to the whole device without any further specification of which lead is affected by the event. The first lead refers to the lead with the smallest associated RT-SA object handle attribute value. The second lead refers to the lead with the second smallest associated RT-SA object handle attribute value. The third lead refers to the lead with the largest associated RT-SA object handle attribute value. The specific bit mappings of BasicECGDevStat are defined in B.1.

NOTE—If the lead unspecified bit is set and multiple leads are implemented, the manager cannot determine whether any of the implemented leads provide useful data.

6.9.3 Context Data Trigger

The Context Data Trigger enumeration object informs the user of the reason for transmitted segments of ECG waveform, heart rate, or R-R interval measurement data, such as a user pressing a button or an automatic event due to a data analysis mechanism in the agent (e.g., in case of detection of a cardiac event). The nomenclature code to identify the enumeration object class is MDC_MOC_VMO_METRIC_ENUM. Refer to Table 12 for the set of attributes of this object.

Table 12 —Context Data Trigger enumeration object attributes

Attribute name	Extended configuration	
	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M
Type	{MDC_PART_PHD_DM, MDC_ECG_EVT_CTXT_GEN}	M
Supplemental-Types	See IEEE Std 11073-20601a-2010.	NR
Metric-Spec-Small	See IEEE Std 11073-20601a-2010.	M
Metric-Structure-Small	See IEEE Std 11073-20601a-2010.	NR
Measurement-Status	See IEEE Std 11073-20601a-2010.	O
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.	C
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 and the following text.	M
Enum-Observed-Value-Simple-Bit-Str	See IEEE Std 11073-20601a-2010.	NR
Enum-Observed-Value-Basic-Bit-Str	See IEEE Std 11073-20601a-2010.	NR
Enum-Observed-Value-Simple-Str	See IEEE Std 11073-20601a-2010.	NR
Enum-Observed-Value	See IEEE Std 11073-20601a-2010.	NR
Enum-Observed-Value-Partition	See IEEE Std 11073-20601a-2010.	NR

NOTE 1—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

The codes used for the Enum-Observed-Value-Simple-OID shall be one of the codes defined in Table 13.

Table 13 —Nomenclature codes for data trigger context

Description/definition	Reference ID	Code
User triggered event (e.g., user press a button)	MDC_ECG_EVT_CTXT_USER	21978
Periodic scheduled event	MDC_ECG_EVT_CTXT_PERIODIC	21979
Detected unspecific cardiac event	MDC_ECG_EVT_CTXT_DETECTED	21980
External event (triggered by an external function, e.g., by a pulse oximeter or blood pressure sensor in a multifunction agent)	MDC_ECG_EVT_CTXT_EXTERNAL	21981

The triggering of transmitting measurement data can occur at any arbitrary point of time. The time stamp used shall be equal to the first measurement data sample that is transmitted in the context of the event.

NOTE 2—The current data trigger context attribute as defined in this standard is general with respect to the specificity of detected cardiac events. Future standardization work might result in additional levels of specificity, providing more detailed information on the specific cause of the event.

6.10 PM-store objects

6.10.1 General

In the context of personal health devices, basic ECG agent devices are portable or mobile devices. As stated in 5.1, basic ECG agents may be used to collect measurements or observations at a time when out of the network and agent/manager associations cannot be established. It is also common that a given set of measurements or observations made by basic ECG agents may need to be uploaded to more than one manager, for example, in the home and at a medical facility.

In order to be suitable for a wide range of devices with different extents of complexity and feature sets, this standard supports agent-initiated transmission of temporarily stored data and transmission of streaming data by use of scanner objects as well as manager-initiated transmission of data recorded in PM-stores. Any configuration not including a PM-store object shall utilize agent-initiated event reports or scanner objects to transmit the measurements or 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 upon upload. Alternatively, any configuration with a PM-store for longer term storage shall disable agent-initiated transmission as well as the use of scanner objects and support manager-initiated transmission of data recorded in PM-stores.

The data held in PM-store objects may be deleted by user actions via the manager or user interface on the device, and the capacity is limited only by the agent's data storage capabilities.

6.10.2 Persistent store model

The PM-store model defined by this standard utilizes two optional PM-store objects, the periodic PM-store object for the persistent storage of periodic data, as for example, ECG waveform measurements or periodic heart rate measurements, and the aperiodic PM-store object for aperiodic data related for example to device status enumerations (see Figure 6). Note that the PM-store object is not part of standard configurations defined in this standard. An agent that supports PM-store and that has a type value set to DEV_SUB_SPEC_PROFILE_ECG shall implement the periodic PM-store object.
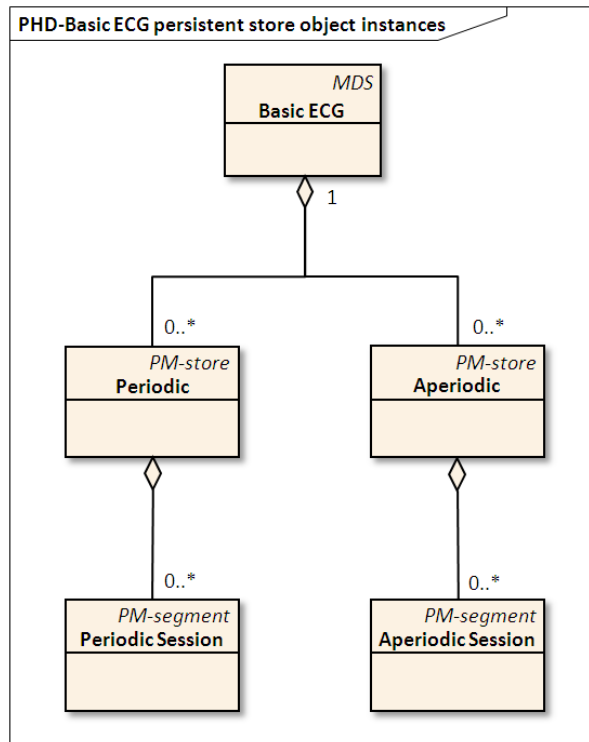
Figure 6—Basic ECG (1- to 3-lead ECG)—persistent store model

Following the guidelines provided in this standard should enable an implementer to store and retrieve the data within this model, but the specifics for determining the specific nature of the data layout and the subsequent visualization, mining, or other managing of the retrieved data is outside the scope of this standard. For a 3-lead basic ECG device, Figure 7 shows an example layout. In this example, the agent implements a periodic PM-store object for the persistent storage of ECG waveform data. Several segments are implemented to account for the data collection of several sessions. Within a segment, several entries are used to account for the amount of data stored. Each entry contains waveform measurements of a certain period in time for all three ECG leads. For each lead, the measured waveform data are contained in one element of the entry.
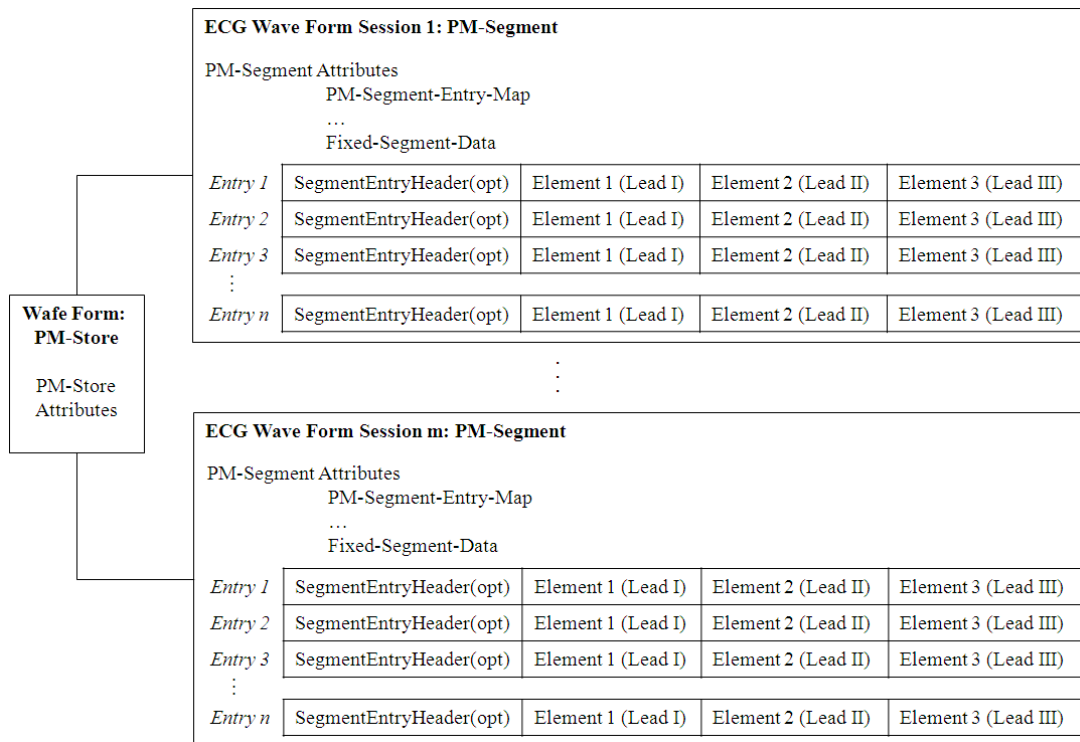
Figure 7—Example: Periodic PM-store with multiple sessions of waveform data for a 3-lead basic ECG device

6.10.3 Periodic

Table 14 summarizes the attributes of the periodic PM-store object. The nomenclature code to identify the PM-store object is MDC_MOC_VMO_PMSTORE.

Table 14—Periodic 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.	O
Sample-Period	See IEEE Std 11073-20601a-2010.	C
Number-Of-Segments	See IEEE Std 11073-20601a-2010.	M
Clear-Timeout	See IEEE Std 11073-20601a-2010.	M

The PM-Store-Capab attribute shall set the following bits as indicated:

— **pmsc-var-no-of-segm:**
If the agent creates new segments either due to storing data of multiple sessions or 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.

— **pmsc-epi-seg-entries:**
The pmsc-epi-seg-entries bit shall not be set.

— **pmsc-peri-seg-entries:**
The pmsc-peri-seg-entries bit shall be set.

The remaining bits of the PM-Store-Capab attribute are agent specific and shall be set appropriately.

NOTE 1—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

NOTE 2—See 6.3 for a description of the qualifiers.

6.10.4 Aperiodic

Table 15 summarizes the attributes of the aperiodic PM-store object. The nomenclature code to identify the PM-store object is MDC_MOC_VMO_PMSTORE.

Table 15—Aperiodic 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.	O
Sample-Period	See IEEE Std 11073-20601a-2010.	NR
Number-Of-Segments	See IEEE Std 11073-20601a-2010.	M
Clear-Timeout	See IEEE Std 11073-20601a-2010.	M

The PM-Store-Capab attribute shall set the following bits as indicated:

— **pmsc-var-no-of-segm:**
If the agent creates new segments either due to storing data of multiple sessions or 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.

— **pmsc-epi-seg-entries:**
The pmsc-epi-seg-entries bit shall be set.

— **pmsc-peri-seg-entries:**
The pmsc-peri-seg-entries bit shall not be set.

The remaining bits of the PM-Store-Capab attribute are agent specific and shall be set appropriately.

NOTE 1—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

NOTE 2—See 6.3 for a description of the qualifiers.

6.10.5 PM-store object methods

This subclause applies to both periodic as well as aperiodic PM-store objects. Table 16 defines the methods of a PM-store object.

Table 16 — 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	
	Get-Segment-Info	Confirmed	MDC_ACT_SEG_GET_INFO	SegmSelection	SegmentInfoList
	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 a PM-segment object. The agent shall support the Clear-Segments method by setting the pmsc-clear-segm-by-all-sup bit for the PM-Store-Capab attribute. Deletion of PM-segments is not guaranteed by this method. See IEEE Std 11073-20601a-2010 for information on how the agent shall reply in case it decides to protect certain segments from deletion.

Get-Segment-Info

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

Trig-Segment-Data-Xfer

This method allows the manager to initiate the transfer of the data entries stored in a PM-segment object.

Refer to IEEE Std 11073-20601a-2010 for details.

6.10.6 PM-store object events

This subclause applies to both periodic as well as aperiodic PM-store objects. Table 17 defines the events sent by PM-store objects.

Table 17 — 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 a PM-segment object. This event is triggered by the manager using the Trig-Segment-Data-Xfer action. Refer to IEEE Std 11073-20601a-2010 for details.

6.10.7 PM-store object services

6.10.7.1 General

This subclause applies to both periodic as well as aperiodic PM-store objects.

6.10.7.2 GET service

The GET service shall be provided by an agent implementing PM-store objects. This service shall be available only while the agent is in the Operating state. Refer to IEEE Std 11073-20601a-2010 for details.

6.10.7.3 SET service

There are currently no SET services defined for PM-store objects in this standard.

6.10.8 PM-segment objects

6.10.8.1 Periodic session

Table 18 defines the attributes of the periodic session PM-segment object contained in the periodic PM-store object managing the stored measurements or observations. The nomenclature code to identify the PM-segment class is MDC_MOC_PM_SEGMENT.

Table 18 —Periodic session 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
Operational-State	See IEEE Std 11073-20601a-2010.	M
Sample-Period	See IEEE Std 11073-20601a-2010.	C
Segment-Label	See IEEE Std 11073-20601a-2010.	O
Segment-Start-Abs-Time	See IEEE Std 11073-20601a-2010.	C
Segment-End-Abs-Time	See IEEE Std 11073-20601a-2010.	C
Date-and-Time-Adjustment	See IEEE Std 11073-20601a-2010.	C
Segment-Start-BO-Time	See IEEE Std 11073-20601a-2010.	C
Segment-End-BO-Time	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	See IEEE Std 11073-20601a-2010.	M
Confirm-Timeout	See IEEE Std 11073-20601a-2010.	O
Transfer-Timeout	See IEEE Std 11073-20601a-2010.	M

NOTE 1—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

NOTE 2—See 6.3 for a description of the qualifiers.

If an agent does not implement the Sample-Period attribute of the periodic PM-store object, then it shall implement the Sample-Period attribute of the periodic session PM-segment objects. If an agent does

implement the Sample-Period attribute of the periodic PM-store object, then it shall not implement the Sample-Period attribute of the periodic session PM-segment objects. For each implemented periodic session PM-segment object, an agent shall either implement the Segment-Start-Abs-Time attribute and the Segment-End-Abs-Time attribute or it shall implement the Segment-Start-BO-Time attribute and the Segment-End-BO-Time attribute. If Segment-Start-Abs-Time and Segment-End-Abs-Time are used, then absolute time stamps shall be used in the entries of the PM-segment. If Segment-Start-BO-Time and Segment-End-BO-Time are used, then base-offset time stamps shall be used in the entries of the PM-segment.

The Fixed-Segment-Data attribute serves as the container of the stored measurements or observations. 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 contains an optional header and one or more elements. Each element holds data from one or more metric measurements.

6.10.8.2 Aperiodic session

Table 19 defines the attributes of the aperiodic session PM-segment object contained in the aperiodic PM-store object managing the stored measurements or observations. The nomenclature code to identify the PM-segment class is MDC_MOC_PM_SEGMENT.

Table 19 —Aperiodic session PM-segment object attributes

Attribute name	Extended configuration	
	Value	Qual.
Instance-Number	See ISO/IEEE 11073-20601:2010.	M
PM-Segment-Entry-Map	See ISO/IEEE 11073-20601:2010.	M
PM-Seg-Person-Id	See ISO/IEEE 11073-20601:2010.	C
Operational-State	See ISO/IEEE 11073-20601:2010.	M
Sample-Period	See ISO/IEEE 11073-20601:2010.	O
Segment-Label	See ISO/IEEE 11073-20601:2010.	O
Segment-Start-Abs-Time	See ISO/IEEE 11073-20601:2010.	M
Segment-End-Abs-Time	See ISO/IEEE 11073-20601:2010.	M
Date-and-Time-Adjustment	See ISO/IEEE 11073-20601:2010.	C
Segment-Start-BO-Time	See ISO/IEEE 11073-20601:2010.	C
Segment-End-BO-Time	See ISO/IEEE 11073-20601:2010.	C
Segment-Usage-Count	See ISO/IEEE 11073-20601:2010.	M
Segment-Statistics	See ISO/IEEE 11073-20601:2010.	O
Fixed-Segment-Data	See ISO/IEEE 11073-20601:2010.	M
Confirm-Timeout	See ISO/IEEE 11073-20601:2010.	O
Transfer-Timeout	See ISO/IEEE 11073-20601:2010.	M

NOTE 1—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

NOTE 2—See 6.3 for a description of the qualifiers.

For each implemented aperiodic session PM-segment object, an agent shall either implement the Segment-Start-Abs-Time attribute and the Segment-End-Abs-Time attribute or it shall implement the Segment-Start-BO-Time attribute and the Segment-End-BO-Time attribute. For each entry in an implemented aperiodic PM-segment object, an agent shall include one of the time formats in the segm-entry-header.

The Fixed-Segment-Data attribute serves as the container of the stored measurements or observations. 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 contains an optional header and one or more elements. Each element holds data from one or more metric measurements.

6.11 Scanner objects

6.11.1 General

The scanner object class is a powerful construct that enables efficient grouping of several attribute value changes from one or more metric objects into a single event report in a more efficient way than can be done by using MDS events. A scanner implementation is either episodic or periodic. It is also helpful in conveying the continuous nature of annunciations expressed within enumeration objects, as the scanner object can periodically dispatch scan event reports dedicated to a particular part of status recording when the period reported in the Reporting-Interval attribute expires. The information model for the scanner hierarchy is shown in Figure 8, containing two optional scanner objects. PeriCfgScanner objects are used to send reports containing periodic data. EpiCfgScanner objects are used to send reports containing episodic data, that is, data not having a fixed period between each data value. Note that periodic or episodic configurable scanners objects are not part of the standard configurations defined in this standard.
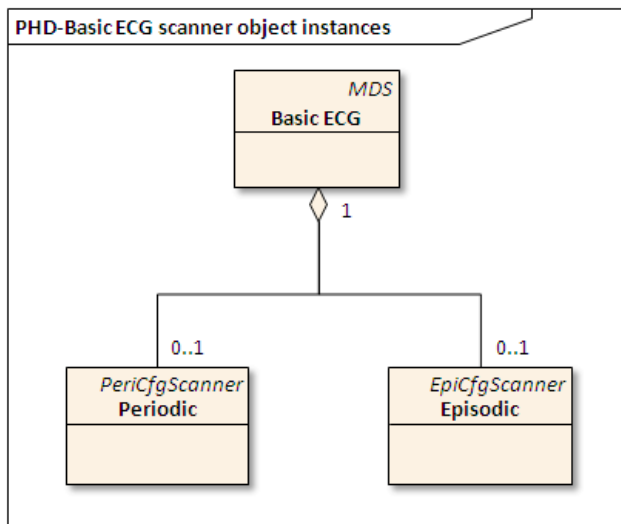
Figure 8—Basic ECG (1- to 3-lead ECG)—scanner model

Figure 9 illustrates an example collection of data that would be periodically transmitted as an associated block of information from a periodic configurable scanner. This construct enables the packaging of data as an associated set of measurements.

Scan report 1	Absolute Time	Heart Rate	Lead I data samples	Lead II data samples	Lead III data samples
Scan report 2	Absolute Time	Heart Rate	Lead I data samples	Lead II data samples	Lead III data samples
Scan report 3	Absolute Time	Heart Rate	Lead I data samples	Lead II data samples	Lead III data samples

Figure 9—Example: Periodic configurable scanner data layout for a 3-lead basic ECG device

Because IEEE Std 11073-20601a-2010 requires the manager to support grouped-format event reports, a manager must support the interpretation of this object class if the agent transmits data using periodic scanner object. Otherwise, if the agent presents the bulk of its data with scanner objects, the manager cannot receive the data presented by such an agent.

6.11.2 Periodic configurable scanner attributes

Table 20 shows the attributes applicable to the periodic configurable scanner object. The nomenclature code to identify the periodic configurable scanner object class is MDC_MOC_SCAN_CFG_PERI.

Table 20 —Periodic configurable scanner object attributes

Attribute name	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M
Operational-State	See IEEE Std 11073-20601a-2010.	M
Scan-Handle-List	See IEEE Std 11073-20601a-2010.	C
Scan-Handle-Attr-Val-Map	See IEEE Std 11073-20601a-2010.	C
Confirm-Mode	See IEEE Std 11073-20601a-2010.	M
Confirm-Timeout	See IEEE Std 11073-20601a-2010.	O
Transmit-Window	See IEEE Std 11073-20601a-2010.	O
Reporting-Interval	See IEEE Std 11073-20601a-2010.	M

NOTE 1—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

NOTE 2—See 6.3 for a description of the qualifiers.

With regard to the Confirm-Mode attribute, an agent may support either or both confirmed or unconfirmed scan reports; the manager shall support both confirmed and unconfirmed scan reports.

A single periodic configurable scanner object may be employed by a basic ECG device in order to reduce the data transmissions between the agent and the manager.

The events in Table 21 define the events sent by the periodic configurable scanner object of the basic ECG (1- to 3-lead ECG) agent.

Table 21 —Periodic configurable scanner object events

Event	Mode	Event type	Event info parameter	Event-reply-info
Buf-Scan-Report-Var	Confirmed or unconfirmed	MDC_NOTI_BUF_SCAN_REPORT_VAR	ScanReportInfoVar	—
Buf-Scan-Report-Fixed	Confirmed or unconfirmed	MDC_NOTI_BUF_SCAN_REPORT_FIXED	ScanReportInfoFixed	—
Buf-Scan-Report-Grouped	Confirmed or unconfirmed	MDC_NOTI_BUF_SCAN_REPORT_GROUPED	ScanReportInfoGrouped	—
Buf-Scan-Report-MP-Var	Confirmed or unconfirmed	MDC_NOTI_BUF_SCAN_REPORT_MP_VAR	ScanReportInfoMPVar	—
Buf-Scan-Report-MP-Fixed	Confirmed or unconfirmed	MDC_NOTI_BUF_SCAN_REPORT_MP_FIXED	ScanReportInfoMPFixed	—
Buf-Scan-Report-MP-Grouped	Confirmed or unconfirmed	MDC_NOTI_BUF_SCAN_REPORT_MP_GROUPED	ScanReportInfoMPGrouped	—

Agents that implement a periodic configurable scanner shall support the SET service for the Operational-State attribute in Table 20.

6.11.3 Episodic configurable scanner attributes

Table 22 shows the attributes applicable to the episodic configurable scanner object. The nomenclature code to identify the episodic configurable scanner is MDC_ MOC_SCAN_CFG_EPI.

Table 22—Episodic configurable scanner object attributes

Attribute name	Value	Qual.
Handle	See IEEE Std 11073-20601a-2010.	M
Operational-State	See IEEE Std 11073-20601a-2010.	M
Scan-Handle_list	See IEEE Std 11073-20601a-2010.	C
Scan-Handle-Attr-Val-Map	See IEEE Std 11073-20601a-2010.	C
Confirm-Mode	See IEEE Std 11073-20601a-2010.	M
Confirm-Timeout	See IEEE Std 11073-20601a-2010.	O
Transmit-Window	See IEEE Std 11073-20601a-2010.	O
Min-Reporting-Interval	See IEEE Std 11073-20601a-2010.	M

NOTE 1—See IEEE Std 11073-20601a-2010 for information on whether an attribute is static or dynamic.

NOTE 2—See 6.3 for a description of the qualifiers.

With regard to the Confirm-Mode attribute, an agent may support either or both confirmed or unconfirmed scan reports; the manager shall support both confirmed and unconfirmed scan reports.

The events in Table 23 define the events sent by the episodic configurable scanner object of the basic ECG (1- to 3-lead ECG) agent.

Table 23—Episodic configurable scanner object events

Event	Mode	Event type	Event info parameter	Event-reply-info
Unbuf-Scan-Report-Var	Confirmed or unconfirmed	MDC_NOTI_UNBUF_SCAN_REPORT _VAR	ScanReportInfoVar	—
Unbuf-Scan-Report-Fixed	Confirmed or unconfirmed	MDC_NOTI_UNBUF_SCAN_REPORT _FIXED	ScanReportInfoFixed	—
Unbuf-Scan-Report-Grouped	Confirmed or unconfirmed	MDC_NOTI_UNBUF_SCAN_REPORT _GROUPED	ScanReportInfoGrouped	—
Unbuf-Scan-Report-MP-Var	Confirmed or unconfirmed	MDC_NOTI_UNBUF_SCAN_REPORT _MP_VAR	ScanReportInfoMPVar	—
Unbuf-Scan-Report-MP-Fixed	Confirmed or unconfirmed	MDC_NOTI_UNBUF_SCAN_REPORT _MP_FIXED	ScanReportInfoMPFixed	—
Unbuf-Scan-Report-MP-Grouped	Confirmed or unconfirmed	MDC_NOTI_UNBUF_SCAN_REPORT _MP_GROUPED	ScanReportInfoMPGrouped	—

Agents that implement an episodic configurable scanner shall support the SET service for the Operational-State attribute in Table 22.

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6.12 Class extension objects

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

6.13 Basic ECG (1- to 3-lead ECG) information model extensibility rules

The basic ECG (1- to 3-lead ECG) domain information model of this standard may be extended by including elements defined in IEEE Std 11073-20601a-2010 as well as vendor-specific elements. Any object or attribute extensions implemented should follow the guidelines of this standard as closely as possible.

A basic ECG (1- to 3-lead ECG) 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. Basic ECG (1- to 3-lead ECG) 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 a basic ECG (1- to 3-lead ECG) 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 basic ECG (1- to 3-lead ECG).

The following generic object access services are supported by a basic ECG (1- to 3-lead ECG) agent according to this standard:

— GET service: used by the manager to retrieve the values of the agent MDS object or PM-store attributes. The list of basic ECG (1- to 3-lead ECG) attributes is given in 6.6.1 for the MDS object and in 6.10.3 and 6.10.4 for the PM-store objects.

— SET service: used by the manager to set the values of the agent object attributes. For a basic ECG (1- to 3-lead ECG) agent according to this standard, the Operational-State attributes in Table 20 and Table 22 of the periodic configurable scanner and episodic configurable scanner objects are the only settable attributes.

— Event report service: used by the agent to send configuration reports and measurement data to the manager. The list of event reports for the basic ECG (1- to 3-lead ECG) device specialization is given for the MDS object in 6.6.4, for the PM-store object in 6.10.6, for the scanner objects in 6.11.2 and 6.11.3.

— Action service: used by the manager to invoke actions (or methods) supported by the agent. The list of MDS objects actions for setting the time is given in 6.6.3. The list of PM-store object actions is given in 6.10.5.

Table 24 summarizes the object access services described in this standard.

Table 24—Basic ECG (1- to 3-lead ECG) 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 attributes of the MDS object in the agent.
	<na>	<implied Confirmed>	<na>	GetArgumentSimple = (obj-handle = *handle of PM-store object*), attribute-id-list *optional*	GetResultSimple = (obj-handle = *handle of PM-store object*), attribute-list	Allows the manager to retrieve the values of attributes of a PM-store object in the agent.
SET	<na>	Confirmed or unconfirmed	<na>	SetArgumentSimple = (obj-handle = *handle of scanner object*)	SetResultSimple = (obj-handle = *handle of scanner object*)	Allows the manager to initiate and end data retrieval via a scanner object of the agent.
EVENT REPORT	MDS-Configuration-Event	Confirmed or unconfirmed	MDC_NOTI_CONFIG	ConfigReport	ConfigReport Rsp	Configuration Report to inform manager of the configuration of the agent.
	MDS-Dynamic-Data-Update-Var	Confirmed or unconfirmed	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-Dynamic-Data-Update-Fixed	Confirmed or unconfirmed	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-Dynamic-Data-Update-MP-Var	Confirmed or unconfirmed	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-Dynamic-Data-Update-MP-Fixed	Confirmed or unconfirmed	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.
	Segment-Data-Event	Confirmed	MDC_NOTI_SEGMENT_DATA	SegmentDataEvent	SegmentData Result	PM-store object event to provide data stored in the Fixed-Segment-Data of a PM-segment from the agent to the manager.
	Unbuf-Scan-Report-Var	Confirmed or unconfirmed	MDC_NOTI_UNBUF_SCAN_REPORT_VAR	ScanReportInfoVar	—	Episodic configurable scanner event to provide sets of attribute value changes about any objects and attributes that the scanner monitors.

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Unbuf-Scan-Report-Fixed	Confirmed or unconfirmed	MDC_NOTI_UNBUF_SCAN_REPORT_FIXED	ScanReportInfo Fixed	—	This is the same as Unbuf-Scan-Report-Fixed but with fixed message format for each object.
Unbuf-Scan-Report-Grouped	Confirmed or unconfirmed	MDC_NOTI_UNBUF_SCAN_REPORT_GROUPED	ScanReportInfo Grouped	—	This is the same as Unbuf-Scan-Report-Fixed but with grouped message format.
Unbuf-Scan-Report-MP-Var	Confirmed or unconfirmed	MDC_NOTI_UNBUF_SCAN_REPORT_MP_VAR	ScanReportInfo MPVar	—	This is the same as Unbuf-Scan-Report-Var but allows inclusion of data from multiple persons.
Unbuf-Scan-Report-MP-Fixed	Confirmed or unconfirmed	MDC_NOTI_UNBUF_SCAN_REPORT_MP_FIXED	ScanReportInfo MPFixed	—	This is the same as Unbuf-Scan-Report-Fixed but allows inclusion of data from multiple persons.
Unbuf-Scan-Report-MP-Grouped	Confirmed or unconfirmed	MDC_NOTI_UNBUF_SCAN_REPORT_MP_GROUPED	ScanReportInfo MPGrouped	—	This is the same as Unbuf-Scan-Report-Grouped but allows inclusion of data from multiple persons.
Buf-Scan-Report-Var	Confirmed or unconfirmed	MDC_NOTI_BUF_SCAN_REPORT_VAR	ScanReportInfo Var	—	Periodic configurable scanner event equivalent with Unbuf-Scan-Report-Var but with data buffered over the reporting interval.
Buf-Scan-Report-Fixed	Confirmed or unconfirmed	MDC_NOTI_BUF_SCAN_REPORT_FIXED	ScanReportInfo Fixed	—	Periodic configurable scanner event equivalent with Unbuf-Scan-Report-Fixed but with data buffered over the reporting interval.
Buf-Scan-Report-Grouped	Confirmed or unconfirmed	MDC_NOTI_BUF_SCAN_REPORT_GROUPED	ScanReportInfo Grouped	—	Periodic configurable scanner event equivalent with Unbuf-Scan-Report-Grouped but with data buffered over the reporting interval.
Buf-Scan-Report-MP-Var	Confirmed or unconfirmed	MDC_NOTI_BUF_SCAN_REPORT_MP_VAR	ScanReportInfo MPVar	—	Periodic configurable scanner event equivalent with Unbuf-Scan-Report-MP-Var but with data buffered over the reporting interval.
Buf-Scan-Report-MP-Fixed	Confirmed or unconfirmed	MDC_NOTI_BUF_SCAN_REPORT_MP_FIXED	ScanReportInfo MPFixed	—	Periodic configurable scanner event equivalent with Unbuf-Scan-Report-MP-Fixed, but with data buffered over the reporting interval.
Buf-Scan-Report-MP-Grouped	Confirmed or unconfirmed	MDC_NOTI_BUF_SCAN_REPORT_MP_GROUPED	ScanReportInfo MPGrouped	—	Periodic configurable scanner event equivalent with Unbuf-Scan-Report-MP-Grouped, but with data buffered over the reporting interval.

ACTION	Set-Time	Confirmed	MDC_ACT_SET_TIME	SetTimeInvoke	—	Manager method to invoke the agent to set time in absolute time format to requested value.
	Set-Base-Offset-Time	Confirmed	MDC_ACT_SET_BO_TIME	SetBOTime Invoke	—	Manager method to invoke the agent to set time in base offset time format to requested value.
	Clear-Segments	Confirmed	MDC_ACT_SEG_CLR	SegmSelection	—	Allows the manager to delete data stored in selected PM-segments in the agent.
	Get-Segment-Info	Confirmed	MDC_ACT_SEG_GET_INFO	SegmSelection	SegmentInfoList	Allows the manager to retrieve the value of PM-segment attributes of one or more PM-segments in the agent.
	Trig-Segment-Data-Xfer	Confirmed	MDC_ACT_SEG_TRIG_XFER	TrigSegmData XferReq	TrigSegmData XferRsp	Allows the manager to start the transfer of the Fixed-Segment-Data attribute of a PM-segment in the agent.

7.3 Object access event report services

The event report service (see Table 24) is used by the agent to report its information (e.g., measurements). Event reports in this standard are a property of the MDS object only. The event reports used in this standard are defined in IEEE Std 11073-20601a-2010.

The following conditions apply for a basic ECG (1- to 3-lead ECG) agent according to this standard:

— MDS event reports shall be used in confirmed mode.

— Scanner object event reports may be used in confirmed or unconfirmed mode.

— Agent-initiated mode or persistently stored metric mode shall be supported for measurement data transmission.

A basic ECG (1- to 3-lead ECG) agent, which is designed to operate in an environment where data may be collected from multiple people, may use one of the multiple-person 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. A basic ECG (1- to 3-lead ECG) 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. Basic ECG (1- to 3-lead ECG) communication model

8.1 Overview

This clause describes the general communication model and procedures of the basic ECG (1- to 3-lead ECG) 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 a basic ECG (1- to 3-lead ECG) agent are defined. Small limits allow for simple implementations in terms of low cost and complexity.

A basic ECG (1- to 3-lead ECG) 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 64 512 octets for implementations supporting persistent metric storage. In the absence of the persistent metric storage capability, N_{tx} shall be 7168 octets for implementations supporting the simple ECG profile and 1280 octets for implementations supporting the heart rate profile. For this standard, N_{rx} shall be 256 octets.

For a basic ECG (1- to 3-lead ECG) 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 a basic ECG (1- to 3-lead ECG) 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 basic ECG (1- to 3-lead ECG) 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 basic ECG (1- to 3-lead ECG) specialization, then the field indicating the data request modes (*data-req-mode-capab*) supported by the basic ECG (1- to 3-lead ECG) agent shall be set to *data-req-supp-init-agent*.

9) If the agent supports only the basic ECG (1- to 3-lead ECG) 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) The manager following this specialization shall support protocol-version2. The manager may support additional protocol versions and select them if the agent offers them.

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 basic ECG (1- to 3-lead ECG) specialization, *data-req-initagent-count* shall be 1 and *data-req-init-manager-count* shall be 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 a basic ECG (1- to 3-lead ECG) agent with standard configuration ID 600 (0x0258). Normally, a manager would already know the standard configuration. However, for the purposes of this example, it does not.

8.4.2 Basic ECG (1- to 3-lead ECG)—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 4). For a basic ECG (1- to 3-lead ECG) agent with standard configuration ID 600 (0x258), the format and contents of the configuration notification message are as follows:

```
0xE7  0x00                  APDU CHOICE Type (PrstApdu)
0x00  0x40                  CHOICE.length = 64
0x00  0x3e                  OCTET STRING.length = 66
0x00  0x02                  invoke-id = 2 (start of DataApdu. MDER encoded.)
0x01  0x01                  CHOICE(Remote Operation Invoke | Confirmed Event Report)
0x00  0x38                  CHOICE.length = 56
0x00  0x00                  obj-handle = 0 (MDS object)
0x00  0x00  0x00  0x00      event-time = 0
0x0D  0x1C                  event-type = MDC_NOTI_CONFIG
0x00  0x2e                  event-info.length = 46 (start of ConfigReport)
0x02  0x58                  config-report-id (Dev-Configuration-Id value)
0x00  0x01                  config-obj-list.count = 1 Measurement objects will be "announced"
0x00  0x28                  config-obj-list.length = 40
0x00  0x06                  obj-class = MDC_MOC_VMO_METRIC_NU
0x00  0x01                  obj-handle = 1     (→ 1st Measurement is heart rate)
0x00  0x04                  attributes.count = 4
0x00  0x20                  attributes.length = 32
```

```
0x09 0x2F                 attribute-id = MDC_ATTR_ID_TYPE
0x00 0x04                 attribute-value.length = 4
0x00 0x02 0x4B 0x5C       MDC_PART_SCADA | MDC_ECG_HEART_RATE
0x0A 0x46                 attribute-id = MDC_ATTR_METRIC_SPEC_SMALL
0x00 0x02                 attribute-value.length = 2
0x40 0x40                 Metric-Spec-Small (mss-avail-stored-data, mss-acc-agent-initiated)
0x09 0x96                 attribute-id = MDC_ATTR_UNIT_CODE
0x00 0x02                 attribute-value.length = 2
0x0A 0xA0                 MDC_DIM_BEAT_PER_MIN
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
0x09 0x8F 0x00 0x04       MDC_ATTR_TIME_REL, 4
```

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 4). 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)
0x00 0x00 0x00 0x00       currentTime = 0
0x0D 0x1C                 event-type = MDC_NOTI_CONFIG
0x00 0x04                 event-reply-info.length = 4
0x02 0x58                 ConfigReportRsp.config-report-id = 600
0x00 0x00                 ConfigReportRsp.config-result = accepted-config
```

8.5 Operating procedure

8.5.1 General

Measurement data and status information are communicated from the basic ECG (1- to 3-lead ECG) agent during the Operating state. If not stated otherwise, the operating procedure for a basic ECG (1- to 3-lead ECG) agent of this standard shall be as specified in IEEE Std 11073-20601a-2010.

8.5.2 GET basic ECG (1- to 3-lead ECG) MDS attributes

See Table 5 for a summary of the GET service.

If the *attribute-id-list* field in the roiv-cmip-get service message is empty, the basic ECG (1- to 3-lead ECG) 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 basic ECG (1- to 3-lead ECG) 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 a basic ECG (1- to 3-lead ECG) agent to support this capability. If this capability is not implemented, the basic ECG (1- to 3-lead ECG) agent shall respond as specified in the MDS object attributes clause in IEEE Std 11073-20601a-2010.

8.5.3 Measurement data transmission

See Table 4, Table 17, Table 21, and Table 23 for a summary of the event report services available for measurement data transfer.

To limit the amount of data being transported within an APDU, the basic ECG (1- to 3-lead ECG) 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 or using the PM-store mechanism. If multiple basic ECG (1- to 3-lead ECG) 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 basic ECG (1- to 3-lead ECG) measurement. However, the former strategy is recommended to reduce overall message size and power consumption.

8.6 Time synchronization

Time synchronization between a basic ECG (1- to 3-lead ECG) 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 basic ECG (1- to 3-lead ECG) 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 basic ECG (1- to 3-lead ECG) 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 basic ECG (1- to 3-lead ECG) agent shall send a single simulated heart rate value of 7 bpm (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 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 the IEEE Std 11073-20601a-2010 and ISO/IEEE 11073-104zz documents.

10.3.3 Conformance level 2: Extended nomenclature (ASN.1 and/or ISO/IEEE 11073-10101:2004 [B6])

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 [B6] 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 the IEEE Std 11073-20601a-2010 and/or ISO/IEEE 11073-20101:2004 [B8]. 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, recommended, etc.)—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 25 shows general ICSs.

Table 25—11073-10406 general ICS table

Index[a]	Feature	Reference	Req./Status	Support	Comment
GEN 11073-10406-1	Implementation Description	—	Identification of the device/ application. Description of functionality.		
GEN 11073-10406-2	Standards followed and their revisions	(standard documents)	(set of existing revisions)	(set of supported revision)	
GEN 11073-10406-3	Nomenclature document used and revision	(standard documents)	(set of existing revisions)	(set of supported revisions)	
GEN 11073-10406-4	Conformance Adherence - Level 1 -	See 10.3.2	Base conformance declaration that device meets the following IEEE Std 11073-10406 conformance requirements: a) All mandatory requirements shall be implemented. b) If implemented, conditional, recommended, and optional requirements shall conform to this standard.	Yes/No (No is not expected as No implies that the implementation is non-conformant)	

Index[a]	Feature	Reference	Req./Status	Support	Comment
GEN 11073-10406-5	Conformance Adherence - Level 2 -	See 10.3.3	In addition to GEN 11073-10406-4, 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	
GEN 11073-10406-6	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 11073-10406-7	Nomenclature document used and revision	(standard documents)	(set of existing revisions)	(set of supported revision)	
GEN 11073-10406-8	Data Structure Encoding	—	—	Description of encoding method(s) for ASN.1 data structures	
GEN 11073-10406-9	Use of Private Objects	—	Does the implementation use objects that are not defined in the DIM?	Yes/No (If yes: explain in Table 26)	
GEN 11073-10406-10	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 [B6])? 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 29)	
GEN 11073-10406-11	11073-20601 Conformance		Provide the conformance report required by the IEEE Std 11073-20601a-2010.		

[a]The prefix GEN11073-10406- 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 26.

Table 26 — 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., max. 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 27. A separate MOC attribute ICS shall be provided for each object.

Table 27 — 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.	

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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 28 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 28 —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 MOC 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 29 provides a template for use. One row of the table is to be used for each nomenclature element.

Table 29 —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 60601-2, 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.)

[B3] IEC 62304:2006/EN 62304:2006, Medical device software—Software life-cycle processes.[9]

[B4] IEC 80001-1:2010, Application of risk management for IT-networks incorporating medical devices—Part 1: Roles, responsibilities, and activities.

[B5] ISO 14971:2007, Medical devices—Application of risk management to medical devices.[10]

[B6] ISO/IEEE 11073-10101:2004, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.[11]

[B7] ISO/IEEE 11073-10201:2004, Health informatics—Point-of-care medical device communication—Part 10201: Domain information model.

[B8] ISO/IEEE 11073-20101:2004, Health informatics—Point-of-care medical device communication—Part 20101: Application profile—Base standard.

[B9] ITU-T Rec. X.680-2002, Information technology—Abstract Syntax Notation One (ASN.1): Specification of basic notation.[12]

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[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.in/).

Annex B

(normative)

Any additional ASN.1 definitions

B.1 Bit mappings for device, lead, and signal status

The device status enumeration object requires the following ASN.1 structure definition.

```
BasicECGDevStat ::= BITS-16 {
        leadwire-loss(0)
        leadsignal-loss(1)
        leadwire-loss-first-lead(2)
        leadsignal-loss-first-lead(3)
        leadwire-loss-second-lead(4)
        leadsignal-loss-second-lead(5)
        leadwire-loss-third-lead(6)
        leadsignal-loss-third-lead(7)
                }
```

Annex C

(normative)

Allocation of identifiers

This annex contains the nomenclature codes 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 [B6].

```
/******************************************************************************
* From object infrastructure (MDC_PART_OBJ)
******************************************************************************/
#define MDC_ATTR_TICK_RES                  2693   /*                        */


/******************************************************************************
* From Medical supervisory control and data acquisition (MDC_PART_SCADA)
******************************************************************************/

#define MDC_ECG_TIME_PD_RR_GL              16168  /*                        */


/******************************************************************************
* From Dimensions (MDC_PART_DIM)
******************************************************************************/
#define MDC_DIM_TICK                       6848   /*                        */
#define MDC_DIM_MILLI_VOLT                 4274   /* mV                     */


/******************************************************************************
* From Communication Infrastructure (MDC_PART_INFRA)
******************************************************************************/
#define MDC_DEV_SPEC_PROFILE_ECG           4102   /*                        */
/* 4236 through 4243 used for IEEE Std 11073-10406 (Basic ECG)              */
#define MDC_DEV_SUB_SPEC_PROFILE_ECG       4236   /*                        */
#define MDC_DEV_SUB_SPEC_PROFILE_HR        4237   /*                        */


/******************************************************************************
* From Personal Health Device Disease Management (MDC_PART_PHD_DM)
******************************************************************************/
#define MDC_ECG_DEV_STAT                   21976  /*                        */
#define MDC_ECG_EVT_CTXT_GEN               21977  /*                        */
#define MDC_ECG_EVT_CTXT_USER              21978  /*                        */
#define MDC_ECG_EVT_CTXT_PERIODIC          21979  /*                        */
#define MDC_ECG_EVT_CTXT_DETECTED          21980  /*                        */
#define MDC_ECG_EVT_CTXT_EXTERNAL          21981  /*                        */
#define MDC_ECG_HEART_RATE_INSTANT         21982  /*                        */
```

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 a basic ECG (1- to 3-lead ECG) agent device intends to connect it to a manager device for the first time. The basic ECG (1- to 3-lead ECG) is capable of performing heart rate and R-R interval measurements.

a) When the user connects the basic ECG (1- to 3-lead ECG), 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 several measurements over some period of time. The measurement data are transmitted to the manager using an unconfirmed event reports. See E.5.1 for the corresponding PDU example.

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 several unconfirmed measurements followed by releasing the association.
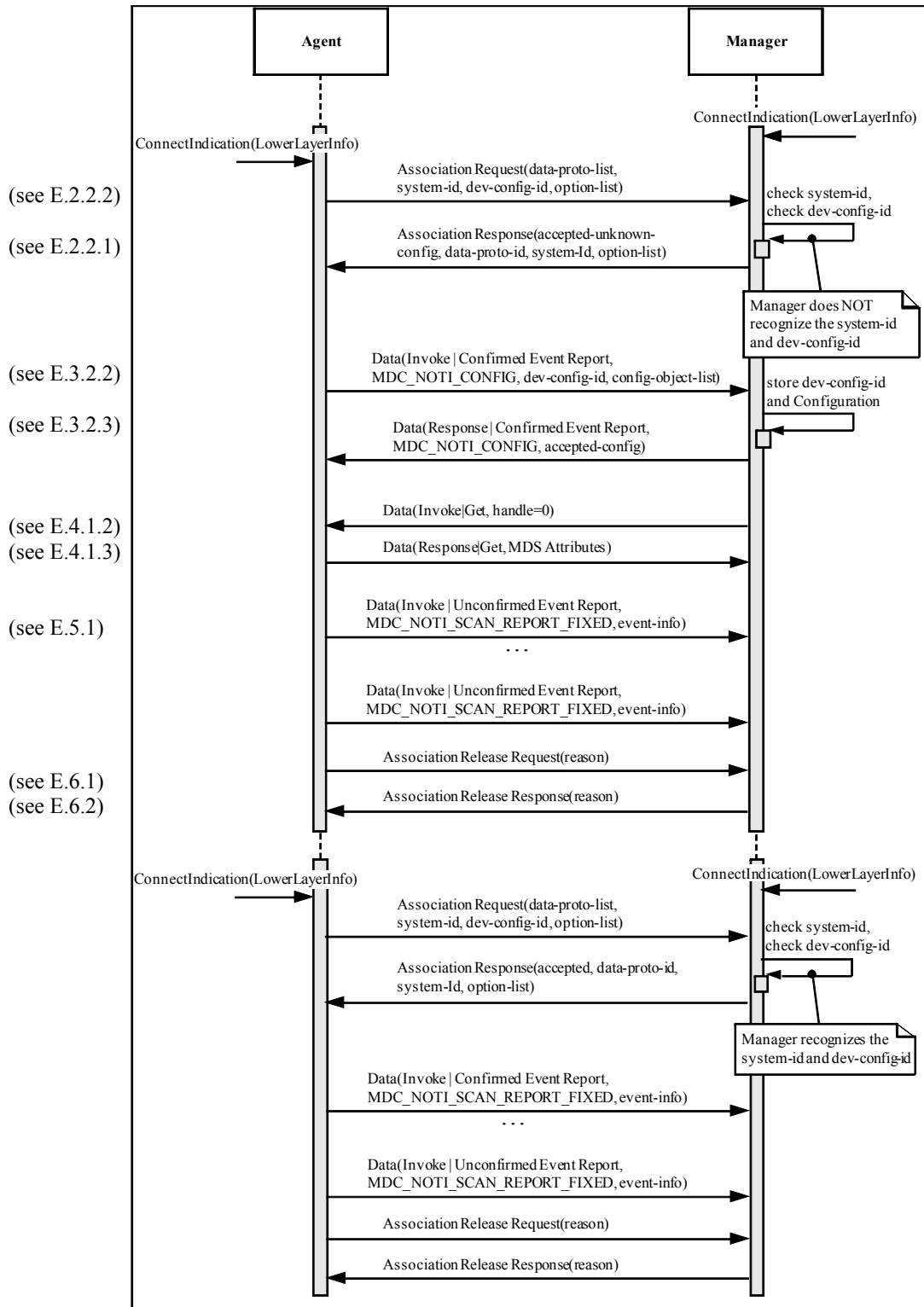
Figure D.1—Sequence diagram for basic ECG (1- to 3-lead ECG) example use case

Annex E

(informative)

Protocol data unit examples

E.1 General

This annex shows binary examples of messages exchanged between a basic ECG (1- to 3-lead ECG) 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 basic ECG (1- to 3-lead ECG) 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
0x80 0x00                encoding rules = MDER
```

```
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)
0x31 0x32 0x33 0x34
0x35 0x36 0x37 0x38
0x40 0x00                  dev-config-id – extended configuration
0x00 0x00                  data-req-mode-flags
0x01 0x00                  data-req-init-agent-count = 1 | data-req-init-manager-count=00x00
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 basic ECG (1- to 3-lead ECG) 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
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)
0x38 0x37 0x36 0x35
0x34 0x33 0x32 0x31
0x00 0x00                  Manager's response to config-id is always 0
0x00 0x00                  data-req-mode-flags
0x00 0x00                  data-req-init-agent-count = 0 | data-req-init-manager-count=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 like E.2.2 has occurred.

E.2.3.2 Association request

The basic ECG (1- to 3-lead ECG) 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
0x80 0x00                    encoding rules = MDER
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)
0x31 0x32 0x33 0x34
0x35 0x36 0x37 0x38
0x40 0x00                    dev-config-id – extended configuration
0x00 0x00                    data-req-mode-flags
0x01 0x00                    data-req-init-agent-count = 1 | data-req-init-manager-count=0
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 basic ECG (1- to 3-lead ECG)'s extended configuration (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
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)
0x38 0x37 0x36 0x35
0x34 0x33 0x32 0x31
0x00 0x00                    Manager's response to config-id is always 0
0x00 0x00                    data-req-mode-flags
0x00 0x00                    data-req-init-agent-count = 0 | data-req-init-manager-count=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 basic ECG (1- to 3-lead ECG) 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
0x80 0x00                encoding rules
0x80 0x00 0x00 0x00      Nomenclature version
0x00 0x00 0x00 0x00      Functional units
0x00 0x80 0x00 0x00      systemType = sys-type-agent
0x00 0x08                system-id length = 8 and value (manufacturer- and device- specific)
0x31 0x32 0x33 0x34
0x35 0x36 0x37 0x38
0x02 0x58                dev-config-id : 600
0x00 0x00                 data-req-mode-flags
0x01 0x00                data-req-init-agent-count = 1 | data-req-init-manager-count=0
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 basic ECG (1- to 3-lead ECG) 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 = 44
0x00 0x03                Result = Accept unknown configuration
0x50 0x79                data-proto-id = 20601
0x00 0x26                data-proto-info length = 38
0x40 0x00 0x00 0x00      protocolVersion
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)
0x38 0x37 0x36 0x35
0x34 0x33 0x32 0x31
0x00 0x00                Manager's response to config-id is always 0
0x00 0x00                data-req-mode-flags
0x00 0x00                data-req-init-agent-count = 0 | data-req-init-manager-count=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

The basic ECG (1- to 3-lead ECG) agent sends the description of its extended 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)
0x00 0x00 0x00 0x00    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 0x01              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 heart rate)
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 0x4B 0x5C    MDC_PART_SCADA | MDC_ ECG_HEART_RATE
0x0A 0x46              attribute-id = MDC_ATTR_METRIC_SPEC_SMALL
0x00 0x02              attribute-value.length = 2
0x80 0x80              stored data, agent init
0x09 0x96              attribute-id = MDC_ATTR_UNIT_CODE
0x00 0x02              attribute-value.length = 2
0x0A 0xA0              MDC_DIM_BEAT_PER_MIN
```

```
0x0A 0x55                    attribute-id = MDC_ATTR_ATTRIBUTE_VAL_MAP
0x00 0x08                    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
0x09 0x91 0x00 0x04          MDC_ATTR_TIME_STAMP_REL, 4
0x00 0x06                    obj-class = MDC_MOC_VMO_METRIC_NU
0x00 0x02                    obj-handle = 2      (→ 2nd Measurement is R-R interval)
0x00 0x05                    attributes.count = 5
0x00 0x24                    attributes.length = 36
0x09 0x2F                    attribute-id = MDC_ATTR_ID_TYPE
0x00 0x04                    attribute-value.length = 4
0x00 0x02 0x3F 0x28          MDC_PART_SCADA | MDC_ECG_TIME_PD_RR_GL
0x0A 0x46                    attribute-id = MDC_ATTR_METRIC_SPEC_SMALL
0x00 0x02                    attribute-value.length = 2
0x88 0x80                    stored data, beat-to-beat metric, agent init
0x09 0x96                    attribute-id = MDC_ATTR_UNIT_CODE
0x00 0x02                    attribute-value.length = 2
0x1A 0xC0                    MDC_DIM_TICK
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
0x09 0x8F 0x00 0x04          MDC_ATTR_TIME_REL, 4
```

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 = 2 (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 = 16384
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 basic ECG (1- to 3-lead ECG) agent responds to the manager with its attributes. Furthermore, some optional fields are communicated as well.

```
0xE7 0x00                    APDU CHOICE Type (PrstApdu)
0x00 0x64                    CHOICE.length = 100
0x00 0x62                    OCTET STRING.length = 98
0x00 0x03                    invoke-id = 3 (mirrored from request)
0x02 0x03                    CHOICE (Remote Operation Response | Get)
0x00 0x5C                    CHOICE.length = 92
0x00 0x00                    handle = 0 (MDS object)
0x00 0x06                    attribute-list.count = 6
0x00 0x56                    attribute-list.length = 86
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 0x8D                    type = MDC_DEV_SUB_SPEC_PROFILE_HR
0x00 0x01                    version = version 1 of the specialization
0x09 0x28                    attribute id = MDC_ATTR_ID_MODEL
0x00 0x22                    attribute-value.length = 34
0x00 0x0A 0x54 0x68          string length = 10 | "TheCompany"
0x65 0x43 0x6F 0x6D
0x70 0x61 0x6E 0x79
0x00 0x14 0x54 0x68          string length = 20 | "TheHeartRateMonitorX"
0x65 0x48 0x65 0x61
0x72 0x74 0x52 0x61
0x74 0x65 0x4D 0x6F
0x6E 0x69 0x74 0x6F
0x72 0x58
0x09 0x84                    attribute-id = MDC_ATTR_SYS_ID
0x00 0x0A                    attribute-value.length = 10
0x00 0x08 0x31 0x32          octet string length = 8 | EUI-64
0x33 0x34 0x35 0x36
0x37 0x38
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 0x8F                    attribute-id = MDC_ATTR_TIME_REL
0x00 0x02                    attribute-value.length =4
0x00 0x00 0x64 0x00          Relative-Time = 3.2s
0x0A 0x85                    attribute-id = MDC_ATTR_TICK_RES
```

```
0x00 0x04                    attribute-value.length = 4
0x00 0x00 0x04 0x00          Tick-Resolution =  1024 s⁻¹
```

E.5 Data reporting

E.5.1 Unconfirmed measurement data transmission

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

```
0xE7 0x00                    APDU CHOICE Type (PrstApdu)
0x00 0x38                    CHOICE.length = 56
0x00 0x36                    OCTET STRING.length = 54
0x00 0x04                    invoke-id = 4
0x01 0x00                    CHOICE(Remote Operation Invoke | Event Report)
0x00 0x30                    CHOICE.length = 48
0x00 0x00                    obj-handle = 0 (MDS object)
0x00 0x00 0x00 0x00          event-time = 0
0x0D 0x1D                    event-type = MDC_NOTI_SCAN_REPORT_FIXED
0x00 0x26                    event-info.length = 38
0xF0 0x00                    ScanReportInfoFixed.data-req-id = 0xF000
0x00 0x01                    ScanReportInfoFixed.scan-report-no = 1
0x00 0x01                    ScanReportInfoFixed.obs-scan-fixed.count = 3
0x00 0x1E                    ScanReportInfoFixed.obs-scan-fixed.length = 30
0x00 0x01                    ScanReportInfoFixed.obs-scan-fixed.value[0].obj-handle = 1
0x00 0x06                    ScanReportInfoFixed.obs-scan-fixed.value[0]. obs-val-data.length = 6
0x00 0x79                    Basic-Nu-Observed-Value = 121 bpm
0x00 0x00 0xE2 0x90          Relative-Time-Stamp = 7.25 s
0x00 0x02                    ScanReportInfoFixed.obs-scan-fixed.value[0].obj-handle = 2
0x00 0x06                    ScanReportInfoFixed.obs-scan-fixed.value[0]. obs-val-data.length = 6
0x00 0x09                    Basic-Nu-Observed-Value = 512 ticks
0x00 0x00 0xE2 0x90          Relative-Time-Stamp = 7.25 s
0x00 0x02                    ScanReportInfoFixed.obs-scan-fixed.value[0].obj-handle = 2
0x00 0x06                    ScanReportInfoFixed.obs-scan-fixed.value[0]. obs-val-data.length = 6
0x00 0x08                    Basic-Nu-Observed-Value = 509 ticks
0x00 0x00 0xF2 0x19          Relative-Time-Stamp = 7.747125 s
```

E.6 Disassociation

E.6.1 Association release request

The basic ECG (1- to 3-lead ECG) 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

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

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Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, a normative definition of the communication between personal basic electrocardiograph (ECG) 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 is established in this standard. Appropriate portions of existing standards including ISO/IEEE 11073 terminology and IEEE 11073-20601 information models are leveraged. The use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability is specified. A common core of communication functionality for personal telehealth basic ECG (1- to 3-lead ECG) devices is defined. Monitoring ECG devices are distinguished from diagnostic ECG equipment with respect to including support for wearable ECG devices, limiting the number of leads supported by the equipment to three, and not requiring the capability of annotating or analyzing the detected electrical activity to determine known cardiac phenomena. This standard is consistent with the base framework and allows multifunction implementations by following multiple device specializations (e.g., ECG and respiration rate).

Keywords: basic electrocardiograph (ECG) (1- to 3-lead ECG), IEEE 11073-10406, medical device communication, personal health devices.