

Health informatics—Point-of-care medical device communication

Part 10201: Domain Information Model

IEEE Engineering in Medicine and Biology Society

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IEEE 11073™ Standards Committee



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Abstract: Within the context of the ISO/IEEE 11073 family of standards for point-of-care medical device communication, an abstract, object-oriented domain information model that specifies the structure of exchanged information, as well as the events and services that are supported by each type of object, is provided in this standard. All data structure elements are specified using abstract syntax (ASN.1) and may be applied to many different implementation technologies, transfer syntaxes, and application service models. Core subjects include medical, alert, system, patient, control, archival, communication, and extended services. Model extensibility is supported, and a conformance model and statement template is provided.

Keywords: abstract syntax, alarm, alert, ASN.1, DIM, domain information model, IEEE 11073-10201™, information model, medical device communications, medical information bus, MIB, object-oriented, patient, POC, point-of-care, remote control

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Introduction

This introduction is not part of IEEE Std 11073-10201-2018, Health informatics—Point-of-care medical device communication—Part 10201: Domain Information Model.

ISO/IEEE 11073 standards enable communication between different medical devices and between medical devices and other IT systems for information and for command and control. The primary goals are to:

- Provide real-time plug-and-play interoperability for patient-connected medical devices
- Facilitate the efficient exchange of patient related data and medical device related data, acquired at the point-of-care (POC), in all health care environments

“Real-time” means that data from multiple devices can be retrieved, time correlated, and displayed or processed in fractions of a second.

“Plug-and-play” means that when a device or system is connected to another device or system, detection, configuration, and the initiation of communication all occur automatically and without any other human interaction.

“Efficient exchange of medical device data” means that information that is captured at the POC (e.g., patient vital signs data) can be archived, retrieved, and processed by many different types of applications without extensive software and equipment support, and without needless loss of information. This standard is especially targeted at acute and continuing care devices, such as patient monitors, ventilators, infusion pumps, ECG devices, etc. It is a member of a family of standards that can be layered together to provide connectivity optimized for the specific devices being interfaced.

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Health informatics—Point-of-care medical device communication

Part 10201: Domain Information Model

1. Scope

The scope of this project is to define a general object-oriented information model that may be used to structure information and identify services used in point-of-care (POC) medical device communications. The scope is primarily focused on acute care medical devices and the communication of patient vital signs information.

~~Within the context of the ISO/IEEE 11073 family of standards, this standard addresses the definition and structuring of information that is communicated or referred to in communication between application entities.~~

~~This standard provides a common representation of all application entities present in the application processes within the various devices independent of the syntax.~~

~~The definition of association control and lower layer communication is outside the scope of this standard.~~

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used, so each referenced document is cited in text and its relationship to this document is explained) ~~standard~~. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments or corrigenda) applies.

~~CEN EN 1064, Medical informatics — Standard communication protocol — computer-assisted electrocardiography.[†]~~

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

~~CEN ENV 12052, Medical informatics—Medical imaging communication (MEDICOM).~~

~~IEEE Std 1073™, IEEE Standard for Medical Device Communications—Overview and Framework.²~~

~~IETF RFC 1155, Structure and Identification of Management Information for TCP/IP-Based Internets.³~~

~~ISO 639-1, Code for the representation of names of languages—Part 1: Alpha-2 code.⁴~~

~~ISO 639-2, Codes for the representation of names of languages—Part 2: Alpha-3 code.~~

~~ISO 3166-1, Codes for the representation of names of countries and their subdivisions—Part 1: Country codes.~~

~~ISO 3166-2, Codes for the representation of names of countries and their subdivisions—Part 2: Country subdivision code.~~

~~ISO 3166-3, Codes for the representation of names of countries and their subdivisions—Part 3: Code for formerly used names of countries.~~

~~ISO 8601, Data elements and interchange formats—Information interchange—Representation of dates and times.~~

~~ISO 15225, Nomenclature—Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange.~~

²~~IEEE publications are available from the Institute of Electrical and Electronics Engineers, 445 Hoes Lane, Piscataway, NJ 08854, USA (<http://www.standards.ieee.org/>).~~

³~~Internet requests for comment (RFCs) are available from the Internet Engineering Task Force at <http://www.ietf.org/>.~~

⁴~~ISO publications are available from the ISO Central Secretariat, Case Postale 56, 1 rue de Varembe, 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, 25 West 43rd Street, 4th Floor, New York, NY 10036, USA ([http://www.ansi.org/](http://www ansi.org/)).~~

~~ISO/IEC 646, Information technology — ISO 7 bit coded character set for information interchange.⁵~~

~~ISO/IEC 2022, Information technology — Character code structure and extension techniques.~~

~~ISO/IEC 5218, Information technology — Codes for the representation of human sexes.~~

~~ISO/IEC 7498-1, Information technology — Open systems interconnection — Basic reference model — Part 1: The basic model.~~

~~ISO/IEC 7498-2, Information processing systems — Open systems interconnection — Basic reference model — Part 2: Security architecture.~~

~~ISO/IEC 7498-3, Information processing systems — Open systems interconnection — Basic reference model — Part 3: Naming and addressing.~~

~~ISO/IEC 7498-4, Information processing systems — Open systems interconnection — Basic reference model — Part 4: Management framework.~~

~~ISO/IEC 8649, Information processing systems — Open systems interconnection — Service definition for the Association Control Service Element.~~

~~ISO/IEC 8650-1, Information technology — Open systems interconnection — Connection Oriented Protocol for the Association Control Service Element — Part 1: Protocol.~~

~~ISO/IEC 8650-2, Information technology — Open systems interconnection — Protocol Specification for Association Control Service Element — Part 2: Protocol Implementation Conformance Statements (PICS) proforma.~~

⁵ISO/IEC documents can be obtained from the ISO office, 1 rue de Varembe, Case Postale 56, CH 1211, Genève 20, Switzerland/Suisse (<http://www.iso.ch/>) and from the IEC office, 3 rue de Varembe, Case Postale 131, CH 1211, Genève 20, Switzerland/Suisse (<http://www.iec.ch/>). ISO/IEC publications are also available in the United States from the Sales Department, American National Standards Institute, 25 West 43rd Street, 4th Floor, New York, NY 10036, USA (<http://www.ansi.org/>).

ISO/IEC 8824-1, Information technology — Abstract Syntax Notation One (ASN.1) — Part 1: Specification of basic notation.¹

~~ISO/IEC 8824-2, Information technology — Abstract Syntax Notation One (ASN.1) — Part 2: Information object specification.~~

~~ISO/IEC 8859-11, Information processing — 8-bit single-byte coded graphic character sets — Part 1 to Part 15: Various alphabets.~~

~~ISO/IEC 9545, Information technology — Open systems interconnection — Application layer structure.~~

~~ISO/IEC 9595, Information technology — Open systems interconnection — Common management information service definition.~~

~~ISO/IEC 9596-1, Information technology — Open systems interconnection — Common Management Information Protocol — Part 1: Specification.~~

~~ISO/IEC 10040, Information technology — Open systems interconnection — Systems management overview.~~

~~ISO/IEC 10164-1, Information technology — Open systems interconnection — Systems management — Part 1: Object management function.~~

~~ISO/IEC 10164-2, Information technology — Open systems interconnection — Systems management — Part 2: State management function.~~

~~ISO/IEC 10164-3, Information technology — Open systems interconnection — System management — Part 3: Attributes for representing relationships.~~

~~ISO/IEC 10164-4, Information technology — Open systems interconnection — Systems management — Part 4: Alarm reporting function.~~

¹ ISO/IEC documents are available from the International Organization for Standardization (<http://www.iso.org/>), the International Electrotechnical Commission (<http://www.iec.ch>), and the American National Standards Institute (<http://www.ansi.org/>).

~~ISO/IEC 10164-5, Information technology — Open systems interconnection — Systems management — Part 5: Event management function.~~

~~ISO/IEC 10164-6, Information technology — Open systems interconnection — Systems management — Part 6: Log control function.~~

~~ISO/IEC 10164-7, Information technology — Open systems interconnection — Systems management — Part 7: Security alarm reporting function.~~

~~ISO/IEC 10164-8, Information technology — Open systems interconnection — Systems management — Part 8: Security audit trail function.~~

~~ISO/IEC 10164-9, Information technology — Open systems interconnection — Systems management — Part 9: Objects and attributes for access control.~~

~~ISO/IEC 10164-10, Information technology — Open systems interconnection — Systems management — Part 10: Usage metering function for accounting purposes.~~

~~ISO/IEC 10164-11, Information technology — Open systems interconnection — Systems management — Part 11: Metric objects and attributes.~~

~~ISO/IEC 10164-12, Information technology — Open systems interconnection — Systems management — Part 12: Test management function.~~

~~ISO/IEC 10164-13, Information technology — Open systems interconnection — Systems management — Part 13: Summarization function.~~

~~ISO/IEC 10164-14, Information technology — Open systems interconnection — Systems management — Part 14: Confidence and diagnostic test categories.~~

~~ISO/IEC 10165-1, Information technology — Open systems interconnection — Structure of management information — Part 1: Management information model.~~

~~ISO/IEC 10165-2, Information technology — Open systems interconnection — Structure of management information — Part 2: Definition of management information.~~

~~ISO/IEC 10646-1, Information technology—Universal multiple octet coded character set (UCS)—
Part 1: Architecture and basic multilingual plane.~~

ISO/IEEE 11073-10101, Health informatics — Point-of-care medical device communication — Part 10101: Nomenclature.²

ISO/IEEE 11073-20101, Health informatics — Point-of-care medical device communication — Part 20101: Application profiles – Base standard.

[OMG[®] Unified Modeling Language[®] \(OMG UML[®]\) 2.5.1.](#)³

~~NEMA PS 3, Digital imaging and communications in medicine (DICOM).~~⁶

3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the ~~purposes~~ ~~purpose~~ of this ~~document~~ ~~standard~~, the following ~~terms and~~ definitions apply. The ~~IEEE Standards~~ ~~Authoritative~~ Dictionary ~~Online~~ ~~of IEEE Standards Terms, Seventh Edition~~, should be referenced for terms not defined in this clause.⁴

agent: Device that provides data in a manager-agent communicating system.

alarm: Signal that indicates abnormal events occurring to the patient or the device system.

² ISO/IEEE documents are available from the International Organization for Standardization (<http://www.iso.org/>) and the Institute of Electrical and Electronics Engineers (<http://standards.ieee.org/>).

³ The OMG UML standard can be freely downloaded at <https://www.omg.org/spec/UML/>

⁴ The *IEEE Standards Dictionary Online* is available at <http://dictionary.ieee.org/>. An IEEE Account is required for access to the dictionary, and one can be created at no charge on the dictionary sign-in page.

⁶ ~~NEMA publications are available from Global Engineering Documents, 15 Inverness Way East, Englewood, Colorado 80112, USA (<http://global.ihs.com/>).~~

alert: Synonym for the combination of patient-related physiological alarms, technical alarms, and equipment-user advisory signals.

alert condition: The active (true) state of a physiologic alarm (primarily related to the patient), technical alarm (primarily related to a device), or an advisory that is typically reported to clinicians, physicians, or other healthcare staff, for responding to patient needs or related workflows.

alert monitor: Object representing the output of an alert ~~a device or~~ system that considers multiple alert conditions in a scope defined by objects that are contained by a single medical device system object. An alert monitor is able to report individual, concurrent alert conditions ~~alarm processor and~~ as well as ~~such~~ the overall ~~device or~~ system alert ~~alarm~~ condition.

alert status: Object representing the output of an alert system ~~alarm process~~ that considers multiple alert ~~all alarm~~ conditions in a scope defined by objects that are contained by either a single virtual medical device object ~~spans one~~ or a single medical device system object. An alert status is able to report concurrent alert conditions ~~more objects~~.

archival: Relating to the storage of data over a prolonged period.

association control service element (ACSE): Method used to establish logical connections between medical device systems ~~(MDSs)~~.

attribute: The definition of a property of an object.

channel: An ~~Umbrella object in the~~ object ~~model~~ that groups together physiological measurement data and any ~~data~~-derived ~~from these~~ data that have a contextual relationship with each other.

class: A model which describes the properties and behaviors of a type of entity found within a problem domain. ~~Description of one or more objects with a uniform set of attributes and services including a description of how to create new objects in the class.~~

class diagram: Diagram showing connections between classes in a system.

communication controller: Part of a medical device system ~~(MDS)~~ responsible for communications.

communication party: Actor of the problem domain that participates in the communication in that domain.

communication role: Role of a party in a communication situation defining the party's behavior in the communication. Associated with a communication role is a set of services that the party provides to other parties.

data agent: As a medical device, a patient data acquisition system that provides the acquired data for other devices.

data format: Arrangement of data in a file or stream.

data logger: A ~~medical~~ device that is functioning in its capacity as a data storage and archival system.

NOTE—There may be several different types of data loggers; clinical, technical, forensic, alarm condition, user logs.⁵

data structure: A data organization format that is implemented by an application ~~Manner in which application entities construct the data set information resulting from the use of an information object.~~

dictionary: Description of the contents of the medical data information base (MDIB) containing vital signs information, device information, demographics, and other elements of the MDIB.

discrete parameter: Measured, calculated, or manually entered value ~~Vital signs measurement~~ that can be expressed as a single numeric or textual value.

Example: A non-invasive systolic blood pressure (measured), cardiac index (calculated), gender male or female.

⁵ Notes in text, tables, and figures of a standard are given for information only and do not contain requirements needed to implement this standard.

domain information model (DIM): The model describing common concepts and relationships for a problem domain.

event: A change in device status that is communicated by a notification reporting service.

event report: Service (~~provided~~ by the common medical device information service element) (~~CMDISE~~) to report an event relating to a managed object instance.

framework: A structure of processes and specifications designed to support the accomplishment of a specific task.

graphic parameter: [Parameter](#) ~~Vital signs measurement~~ that requires [multiple](#) ~~a number of~~ regularly sampled data points in order to be expressed properly.

[Example: A single ECG waveform snippet.](#)

host system: Term used as an abstraction of a medical system to which measurement devices are attached.

~~3.25 information object: An abstract data model applicable to the communication of vital signs information and related patient data. The attributes of an information object definition describe its properties. Each information object definition does not represent a specific instance of real-world data, but rather a class of data that share the same properties.~~

information service element: Instances in the medical data information base (~~MDIB~~).

instance: The realization of an abstract concept or specification, e.g., [class](#) ~~object~~ instance, application instance, information service element instance, virtual medical device [instance, operating](#) (~~VMD~~) instance, ~~class instance, operating instance.~~

[instance method: A procedure or process that defines a behavior exhibited by the instances of a class \(i.e., objects\). Instance methods provide the interface by which the properties of an object may be accessed or modified.](#)

intensive care unit (ICU): The unit within a medical facility in which patients are managed using multiple modes of monitoring and therapy.

interchange format: The representation of the data elements and the structure of the message containing those data elements while in transfer between systems. The interchange format consists of a data set of construction elements and a syntax. The representation is technology specific.

interoperability: The ability of two or more devices or systems to exchange information in a format that is usable by the receivers of the information. ~~Idealized scheme where medical devices of differing types, models, or manufacturers are capable of working with each other, whether connected to each other directly or through a communication system.~~

latency: In a communications scenario, the time delay between sending a signal from one device and receiving it by another device.

lower layers: Layer 1 to Layer 4 of the International Organization for Standardization (ISO)/open systems interconnection (OSI) reference model. These layers cover mechanical, electrical, and general communication protocol specifications.

manager: Device that receives data in a manager-agent communicating system.

manager-agent model: Communication model where one device (i.e., agent) provides data and another device (i.e., manager) receives data.

medical data information base (MDIB): The concept of an object-oriented database storing (at least) vital signs information.

medical device: A device, apparatus, or system used for patient monitoring, treatment, or therapy, which does not normally enter metabolic pathways. For the purposes of this standard, the scope of medical devices is further limited to patient-connected medical devices that provide support for electronic communications.

medical device system (MDS): Abstraction for system comprising one or more medical functions. In the context of this standard, the term is specifically used as an object-oriented abstraction of a device that provides medical information in the form of instances of the classes ~~objects~~ that are defined in this standard.

monitor: A medical device designed to acquire, display, record, and/or analyze patient data and to alert caregivers of events needing their attention.

object: A particular instance of a class. An object represents a physical or logical occurrence of an actual medical device or medical device component. Syn: object instance. ~~A concept, an abstraction, or a thing with crisp boundaries and a meaning for the problem at hand.~~

object instance: See: object.

~~**3.40 object attributes:** Data that, together with methods, define an object.~~

~~**3.41 object class:** A descriptor used in association with a group of objects with similar properties (i.e., attributes), common behavior (i.e., operations), common relationships to other objects, and common semantics.~~

~~**3.42 object diagram:** Diagram showing connections between objects in a system.~~

~~**3.43 object method:** A procedure or process acting upon the attributes and states of an object class.~~

object-oriented analysis: Method of analysis where the problem domain is modelled in the form of classes and the relationships between those classes ~~objects and their interactions.~~

open system: A set of protocols allowing computers of different origins to be linked together.

operation: A function or transformation that may be applied to or by objects ~~in a class~~ (sometimes also called service).

problem domain: ~~The~~ The field of health care under consideration in a modeling process.

protocol: A standard set of rules describing the transfer of data between devices. It specifies the format of the data and specifies the signals to start, control, and end the transfer.

real time: At the time when an event or process occurs.

scanner: An observer and “summarizer” of ~~object~~ attribute values.

scenario: A formal description of a class of business activities including the semantics of business agreements, conventions, and information content.

service: A specific behavior that a communication party in a specific role is responsible for exhibiting.

syntax (i.e., of an interchange format): The rules for combining the construction elements of the interchange format.

system: The demarcated part of the perceivable universe, existing in time and space, that may be regarded as a set of elements and relationships between these elements.

timestamp: An attribute or field in data that denotes the time of data generation.

top class ~~object~~: The ultimate base class for most of the classes ~~all other objects~~ belonging to the domain information ~~one~~ model defined in this standard.

upper layers: Layer 5 to Layer 7 of the International Organization for Standardization (ISO)/open systems interconnection (OSI) reference model. These layers cover application, presentation, and session specifications and functionalities.

virtual medical device (VMD): An abstract representation of a medical-related subsystem of a medical device system-~~(MDS)~~.

virtual medical object (VMO): An abstract representation of an object in the Medical Package of the domain information model-~~(DIM)~~.

vital sign: Clinical information, relating to one or more patients, that is measured by or derived from apparatus connected to the patient or otherwise gathered from the patient.

waveform: Graphic data, typically vital signs data values varying with respect to time, usually presented to the clinician in a graphical form.

3.2 Abbreviations and acronyms

ACSE	association control service element
ASN.1	Abstract Syntax Notation One
BCC	bedside communication controller
BER	-basic encoding rules
BMP	basic multilingual plane
CMDIP	Common Medical Device Information Protocol
CMDISE	common medical device information service element
CMIP	Common Management Information Protocol
CMISE	common management information service element
DCC	device communication controller
DICOM	digital imaging and communications in medicine
DIM	domain information model
EBWW	eyeball and wristwatch
ECG	electrocardiogram
EEG	electroencephalogram
FSM	finite state machine
GMDN	Global Medical Device Nomenclature
GMT	Greenwich mean time

IANA	Internet Assigned Numbers Authority
ICS	implementation conformance statement
ICU	intensive care unit
ID	identifier or identification
LAN	local area network
LSB	least significant bit
<u>MDC</u>	<u>medical device communication</u>
MDIB	<u>medical data information base</u>
MDS	medical device system
MEDICOM	medical imaging communication
MIB or Mib	management information base
MOC	-managed object class
OID	object identifier
OR	operating room
OSI	open systems interconnection
PC	personal computer
PDU	protocol data unit
PM	persistent metric
<u>POC</u>	<u>point of care</u>
SCADA	supervisory control and data acquisition

SCP ECG	Standard Communications Protocol [for computer-assisted] Electrocardiography
SNMP	Simple Network Management Protocol
SNTP	Simple Network Time Protocol
UDI	Unique Device Identification
UML	unified modeling language
UTC	coordinated universal time
VMD	virtual medical device
VMO	virtual medical object
VMS	virtual medical system

4. General requirements

The ISO/IEEE 11073 family of standards is intended to enable medical devices to interconnect and inter-operate with other medical devices and with computerized healthcare information systems in a manner suitable for the clinical environment.

The ISO/IEEE 11073 family is based on an object-oriented systems management paradigm. Data (e.g., measurement, state) is modeled in the form of [classes, instances of which](#) ~~information objects~~ ~~that~~ can be accessed and manipulated using an object access service protocol.

The domain information model (DIM) defines the overall set of [classes](#) ~~information objects~~ and their attributes, methods, and access functions needed for medical device communication ([MDC](#)).

The top-level user requirements are defined in [ISO/IEEE 11073-20101](#),⁶ ~~Std 1073~~,⁷ which also defines the user scenarios covered by the ISO/IEEE 11073 family of standards.

^{6,7}Information on references can be found in Clause 2.

As a part of the ISO/IEEE 11073 family of standards, the primary requirements for the DIM are as follows:

- Define an object-oriented model representing the relevant information (i.e., data) and functions (e.g., device controls) encountered in the problem domain of [MDC](#) ~~medical device-communication~~, including measurement information, contextual data, device control methods, and other relevant aspects.
- Provide detailed specification of the [classes](#) ~~information-objects~~ defined in the object-oriented model, including their attributes and methods.
- Define a service model for communicating medical devices that provides access to the [object instances](#) ~~information-objects~~, their attributes, and their methods.
- Use the nomenclature defined in ISO/IEEE 11073-10101 to identify all data elements in the model.
- Be usable for the definition of data communication protocols as well as for the definition of file storage formats.
- Define conformance requirements.
- Be extensible and expandable to incorporate future needs in the defined modeling framework.

5. Domain information model (DIM)

5.1 General

5.1.1 Modeling concept

The DIM is an object-oriented model that consists of [classifiers](#) ~~objects~~, their attributes, and their methods, which are abstractions of real-world entities in the domain of (vital signs information communicating) medical devices.

The information model and the service model for communicating systems defined and used in this standard are conceptually based on the International Organization for Standardization (ISO)/open systems interconnection (OSI) system management model ([ISO/IEC 7498-1 \[B16\]](#), [ISO/IEC 7498-2 \[B17\]](#), [ISO/IEC 7498-3 \[B18\]](#), [ISO/IEC 7498-4 \[B19\]](#)).⁷ ~~Classes~~ ~~Objects~~ defined in the information model are considered [to model](#) managed (here, medical) objects. For the most part, [the objects](#) ~~they~~ are directly available to management (i.e., access) services provided by the common medical device information service element (CMDISE) as defined in this standard.

For communicating systems, the set of object instances available on any medical device that complies with the definitions of this standard forms the medical data information base (MDIB). The MDIB is a structured collection of managed medical objects representing the vital signs information provided by a particular medical device. Attribute data types, hierarchies, and behavior of objects in the MDIB are defined in this standard.

The majority of [classes](#) ~~objects~~ defined here represent generalized vital signs data and support information. Specialization of these [classes](#) ~~objects~~ is achieved by defining appropriate attributes. [Class](#) ~~Object~~ hierarchies and [associations](#) ~~relations~~ between [classes](#) ~~objects~~ are used to express device configuration and device capabilities.

Example: A generalized object is [instantiated](#) ~~defined~~ to represent vital signs in the form of a real-time waveform. A set of ~~object~~ attributes is used to specify a particular waveform as an invasive arterial blood pressure. The position in the hierarchy of all objects defines the subsystem that derives the waveform.

Figure ~~6.1~~ shows the relation between managed medical objects, MDIB, CMDISE, application processes, and communication systems.

In the case of communicating systems, managed medical objects are accessible only through services provided by CMDISE. The way that these objects are stored in the MDIB in any specific system and the way applications and the CMDISE access these objects are implementation issues and as such not normative.

⁷ [The numbers in brackets correspond to those of the bibliography in Annex A.](#)

In the case of a vital signs archived data format that complies with the definitions in this standard, object instances are stored, together with their dynamic attribute value changes, over a certain time period on archival media. Attribute data types and hierarchies of objects in the archival data format are again defined in this standard.

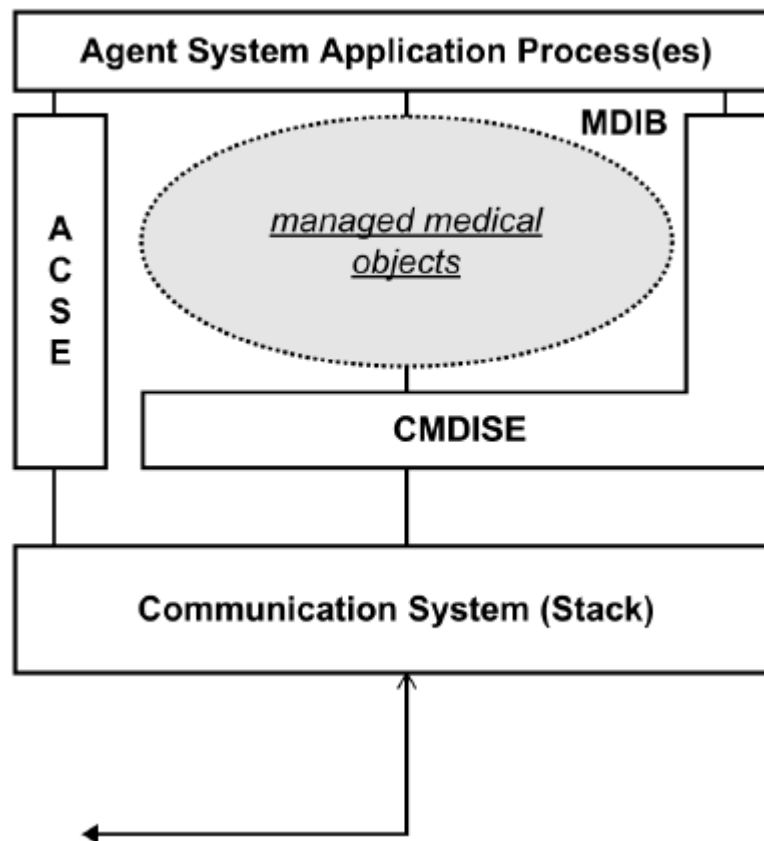


Figure 1—MDIB in communicating systems

Figure 6.2 shows the relationship between managed medical objects, the data archive, and archive access services.

In the case of the archived data format, the way managed medical objects are stored on a medium is the subject of standardization. The access services are a local implementation issue and as such are not intended to be governed by this standard.

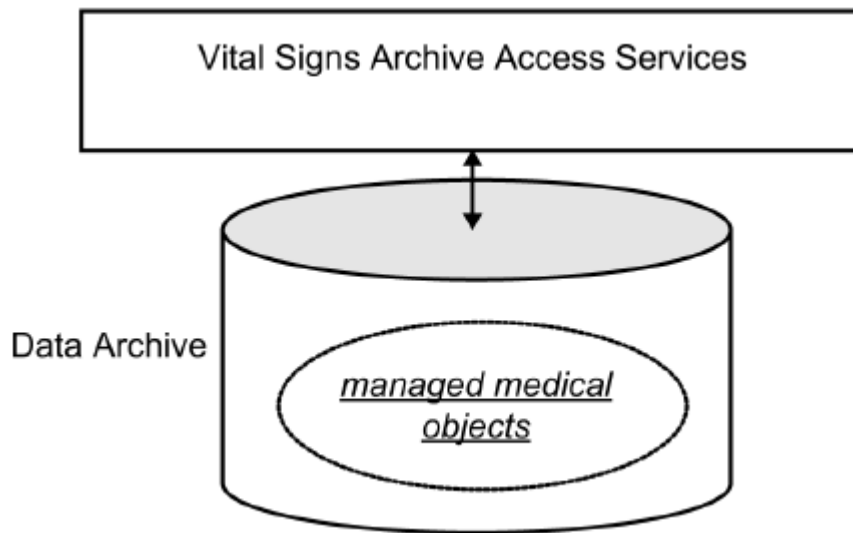


Figure 2—Managed medical objects in a vital signs archive

5.1.2 Scope of the DIM

5.1.2.1 General

Vital signs information [classes](#) ~~objects~~ that are defined in this standard encompass digitized biosignals that are derived by medical measurement devices used, for example, in anaesthesia, surgery, infusion therapy, intensive care, and obstetrical care.

Biosignal data within the scope of this standard include direct and derived, quantitative and qualitative measurements, technical and medical alarms, and control settings. Patient information relevant for the interpretation of these signals is also defined in the DIM.

5.1.2.2 Communicating systems

Communicating systems within the scope of this standard include physiological meters and analysers, especially systems providing real-time or continuous monitoring. Data processing capabilities are required for these systems.

Information management objects that provide capabilities and concepts for cost-effective communication (specifically data summarization objects) and objects necessary to enable real-time communication are also within the scope of the information model in this standard.

Interoperability issues, specifically lower communication layers, temporal synchronization between multiple devices, etc., are outside the scope of this standard.

5.1.2.3 Archived vital signs

Context information [classes](#) ~~objects~~ that describe the data acquisition process and organize a vital signs archive are within the scope of this standard.

5.1.3 Approach

For the object-oriented modeling, the Unified Modeling Language (UML) ~~technique~~ is used. The domain is first subdivided into different packages, and this subdivision permits the organization of the model into smaller packages. Each package is then defined in the form of [UML class](#) ~~object~~ diagrams. [Classes](#) ~~Objects~~ are briefly introduced, and their relations and hierarchies are defined in the [class diagrams. No single ~~object~~ diagram shows all of the classes and relationships defined in the DIM. The diagrams must be considered as a set that, together, define the structure of the DIM.](#)

For the [class](#) ~~object~~ definitions, a textual approach is followed. Attributes are defined in attribute definition tables. Attribute data types are defined using Abstract Syntax Notation One (ASN.1) [as defined by ISO/IEC 8824-1 and ISO/IEC 8824-2 \[B23\]. The](#) behavior of and notifications ~~)-Object~~ generated by objects are also defined in definition tables. These definitions directly relate to the service model specified in Clause [78](#).

5.1.4 Extension of the model

It is expected that over time extensions of the model may be needed to account for new developments in the area of medical devices. Also, in special implementations, there may be a requirement to model data that are specific for a particular device or a particular application (and that are, therefore, not covered by the general model).

In some cases, it may be possible to use the concept of external object relations. Most [classes](#) ~~objects~~ defined in this standard provide an attribute group (e.g., the Relationship Attribute Group) that can be used to supply information about related objects that are not defined in the DIM. Supplying such information can be done by specifying a relation to an external object and assigning attributes to this relation (see [6.7.1.32.20](#)).

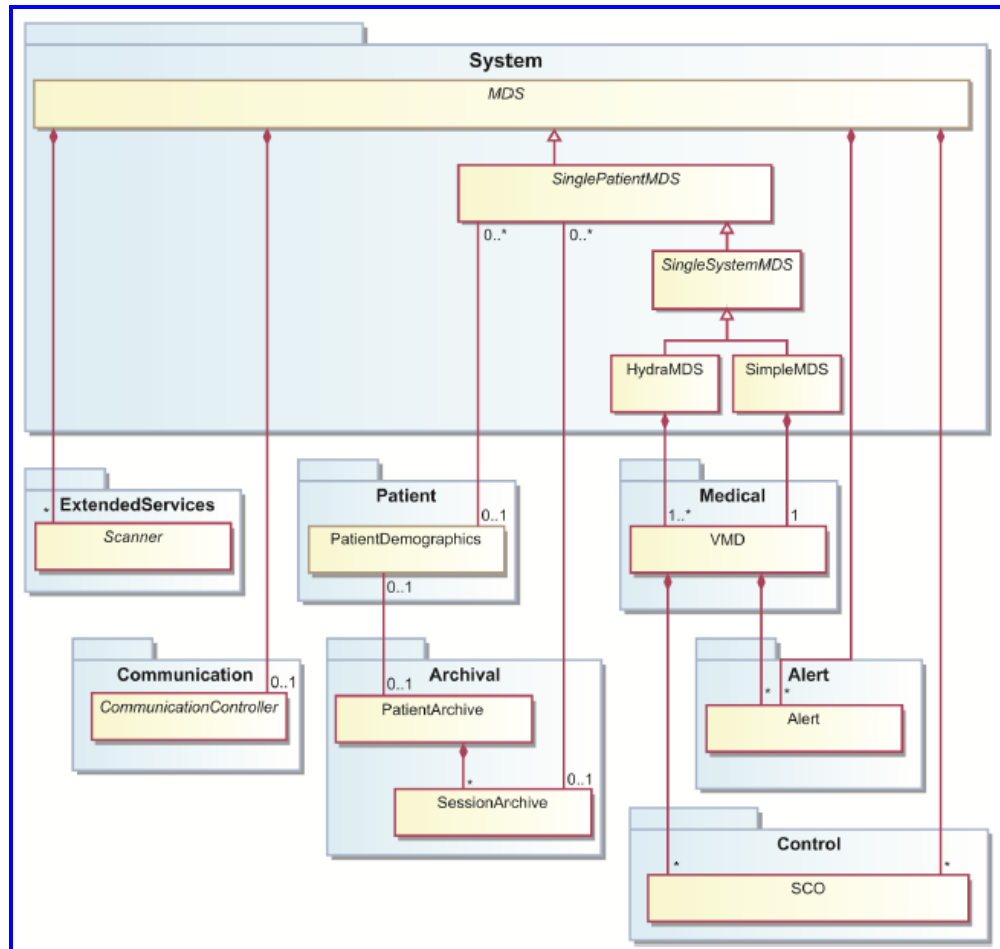
In other cases, it may be necessary to define completely new [classes](#) ~~objects~~ or to add new attributes, new methods, or new events to already defined [classes](#) ~~objects~~. These extensions are considered private or manufacturer-specific extensions. Dealing with these extensions is primarily a matter of an interoperability standard that is based on this standard on vital signs representation.

In general, in an interoperability format, [classes](#), ~~objects~~ attributes, and methods are identified by nomenclature codes. [ISO/IEEE 11073-10101 defines nomenclature that should be preferred when implementing an 11073-compliant device.](#) The nomenclature code space (i.e., code values) leaves room for private extensions. As a general rule, an interoperability standard that is based on this DIM should be able to deal with private or manufacturer-specific extensions by ignoring [classes](#) ~~objects~~, attributes, etc., with unknown identifiers (i.e., nomenclature codes).

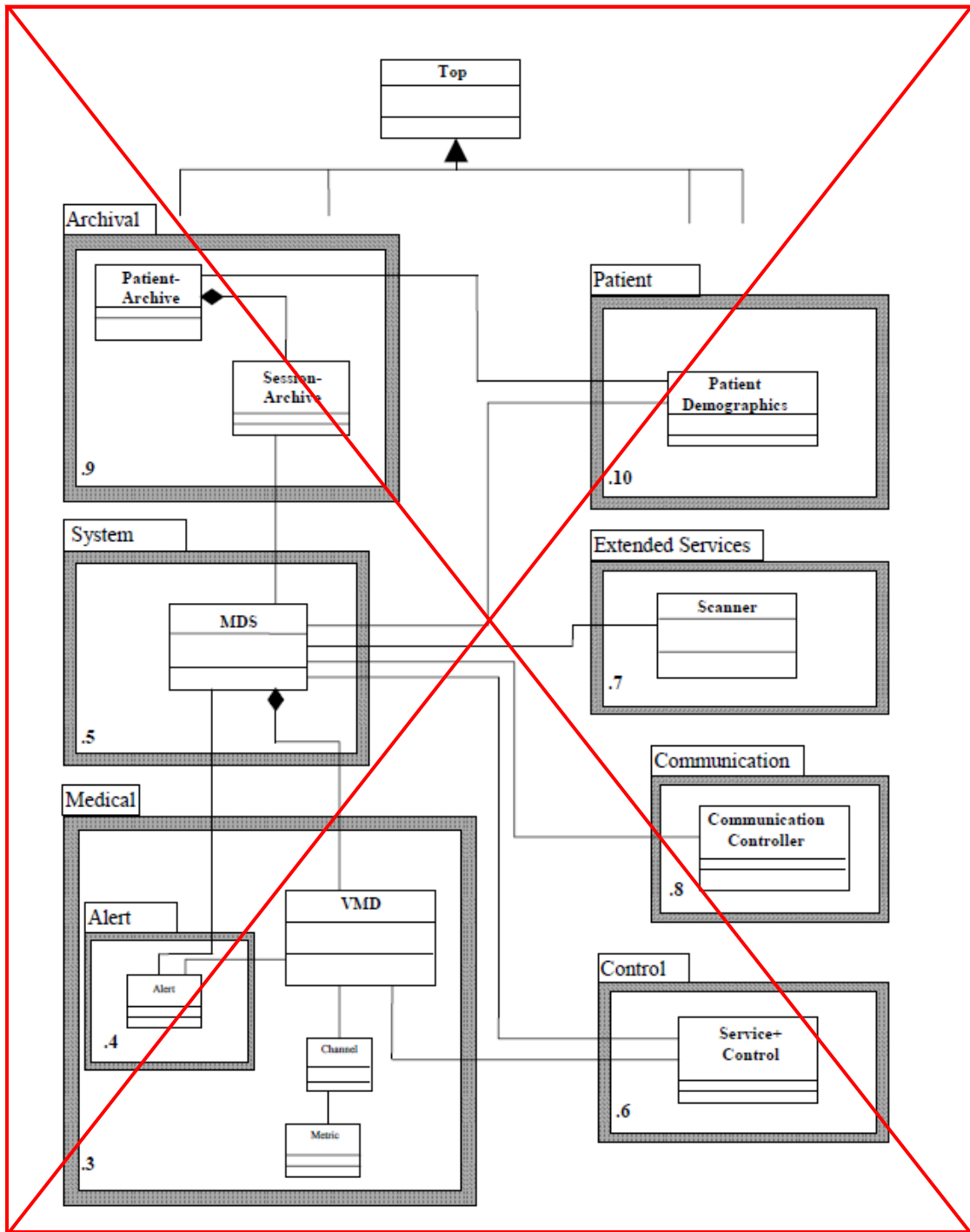
5.2 Package diagram–Overview

The package diagram organizes the problem domain into separate groups. It shows [key classes](#) ~~the major objects~~ inside each package and ~~defines~~ the relationships between [them](#) ~~these packets~~.

The package diagram depicted in Figure 6-3 contains only a small subset of all [classifiers](#) [objects](#) defined in the DIM. ~~Common base objects except the Top object are not shown in this diagram. Also,~~ Not all relations are shown between the [shown classes](#) [different packages](#). Refer to the detailed [UML class package](#) diagrams for [each package](#) for more information.



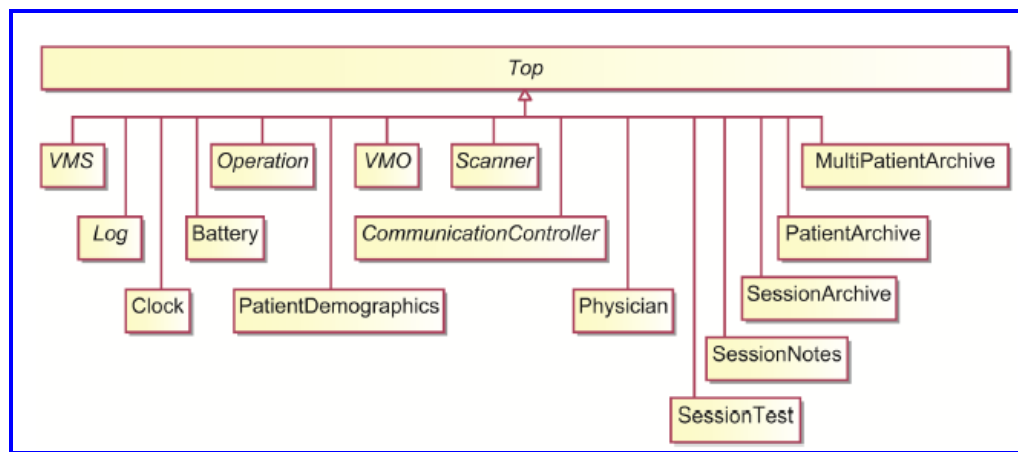
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Figure 3—Packages of the DIM

The Top class is an abstract class and at the same time the ultimate base for the majority of classes defined in the model. The only classes for which the Top class does not serve as a base class are the DeviceInterface class and the MibElement classes. Figure 4 shows the Top class and all of the class that are immediate subclasses of class Top. Many of the subclasses shown are themselves subclassed. This secondary subclassing is not shown in Figure 4.



(New)

Figure 4—Top class inheritance

The more detailed [UML class diagrams](#) ~~models~~ for these packages are contained in [5.6.3](#) through [5.10.6.10](#). These diagrams show relationships between classes defined in the package as well as key relationships between classes defined in the package and classes defined in other packages. Some relationships appear in one diagram and are absent in other diagrams where the two associated classes are shown. The inclusion of a relationship in any UML class diagram indicates that it is part of the complete UML model.

The numbers in the packages refer to the corresponding subclauses in this clause about models and in Clause [6.7](#) about the [class object](#) definitions.

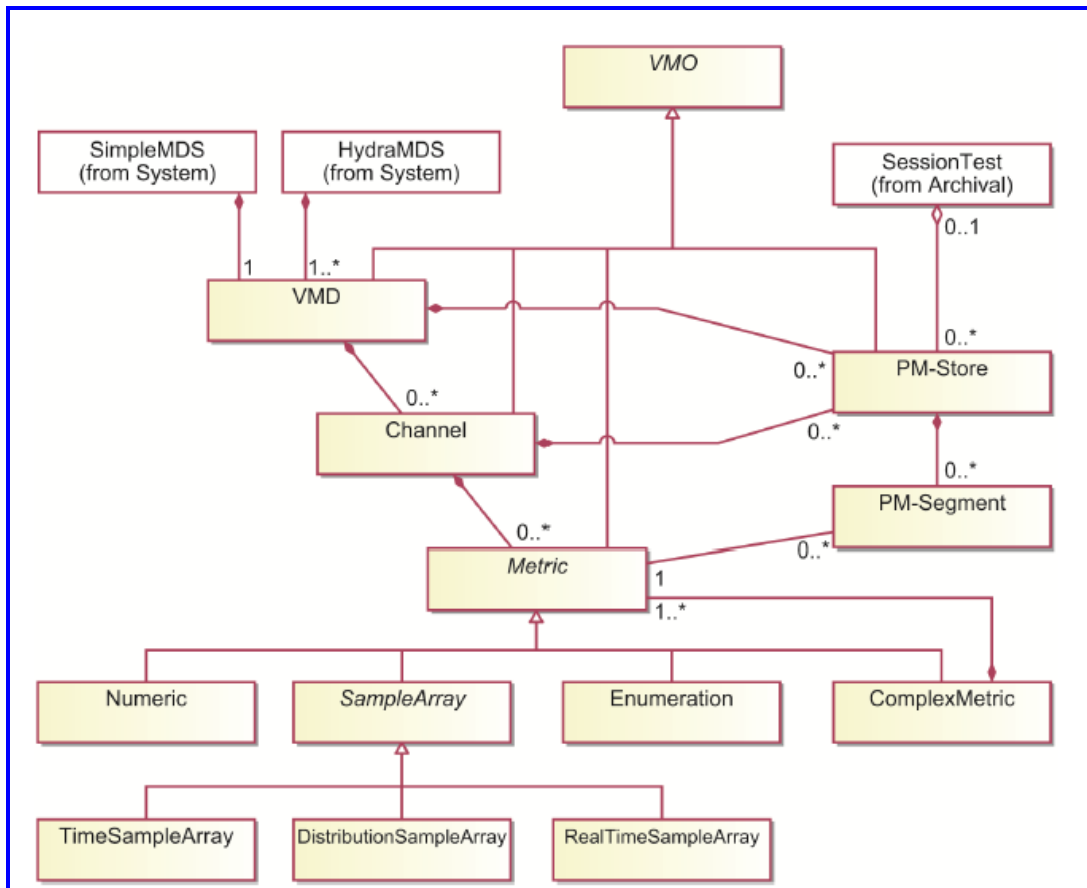
~~The Top object is an abstract base class and at the same time the ultimate base class for all objects defined in the model. For editorial convenience, the modeling diagrams in this standard do not show this inheritance hierarchy.~~

5.3 Model for the Medical Package

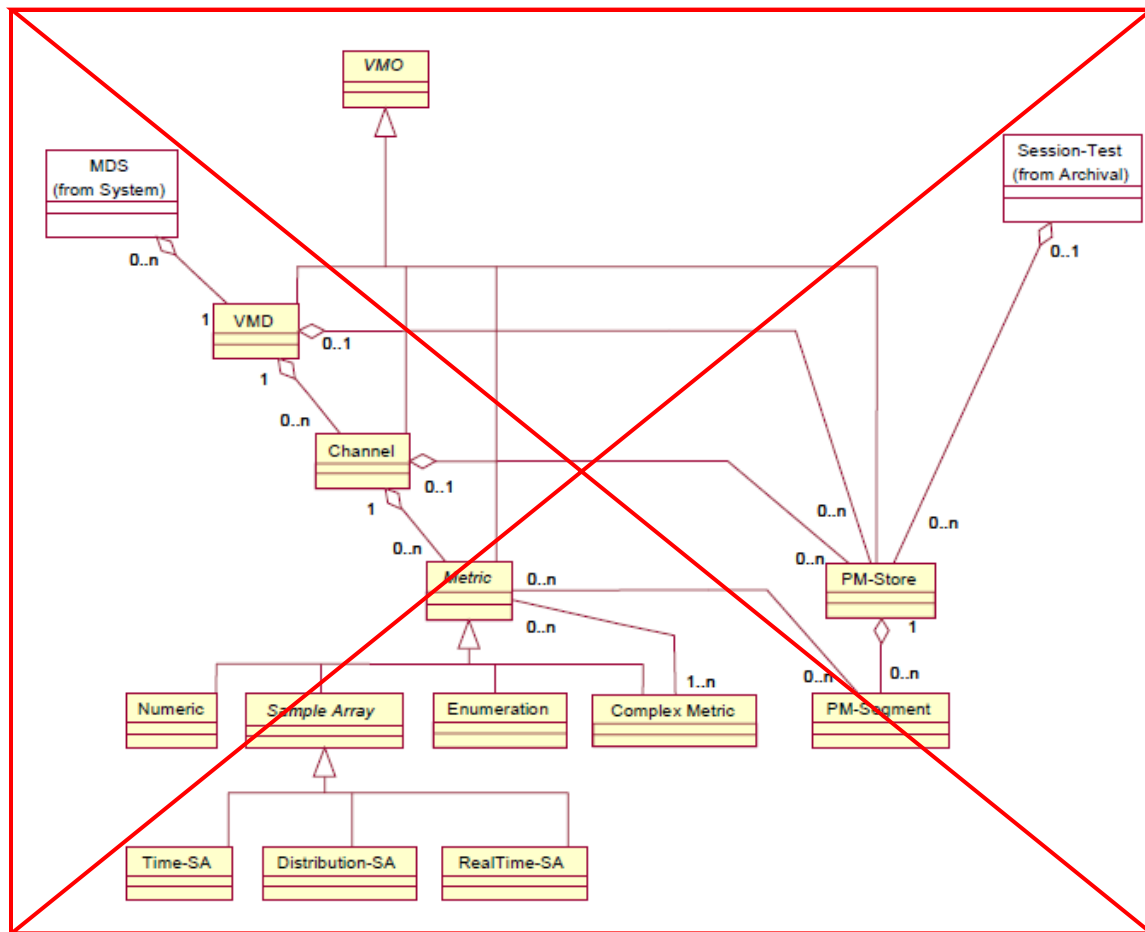
5.3.1 General

The Medical Package deals with the derivation and representation of biosignals and contextual information that is important for the interpretation of measurements.

Figure 56.4 shows the [UML class diagram for object model of](#) the Medical Package.



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Figure 5—Medical Package model

NOTE—Instances of any class that are modeled with a containment association may ~~the Channel~~ object and the PM Store object shall be contained by in exactly one superior object instance of a container class. Refer to the Alert Package for information about alarm related objects.⁸

The Medical Package model contains the classes ~~objects~~ described in 56.3. 24 through 56.3. 1413.

⁸ ~~Notes in text, tables, and figures are given for information only, and do not contain requirements needed to implement the standard.~~

5.3.2 VMO (~~i.e.,~~ virtual medical object) class

~~The~~ VMO is the abstract base class for all medical-related classes ~~objects~~ in the model. It provides consistent naming and identification across the Medical Package model.

The VMO ~~As a base class is abstract and ,the VMO~~ cannot be instantiated.

5.3.3 VMD (~~i.e.,~~ virtual medical device) class ~~object~~

The VMD class models ~~object is an abstraction for a~~ medical-related subsystems ~~subsystem~~ (e.g., hardware or even pure software) of ~~a~~ medical devices. ~~The device~~ characteristics of a ~~this~~ subsystem (e.g., modes, versions) are captured by instances of ~~in~~ this class ~~object~~. At the same time, a ~~the~~ VMD object is a container for objects representing measurement and status information.

Example: A modular patient monitor provides measurement modalities in the form of plug-in modules. Each module is represented by a VMD object.

5.3.4 Channel class ~~object~~

~~The~~ Channel objects are ~~object is~~ used for grouping Metric objects that have ~~and, thus, allows hierarchical information organization. The Channel object is not mandatory for representation of Metric objects in~~ a contextual relationship with each other ~~VMD~~.

Example: A blood pressure VMD may define a Channel object to group together all metrics that deal with the blood pressure (e.g., pressure value, pressure waveform). A second Channel object can be used to group together metrics that deal with heart rate.

The Channel object is mandatory for representation of Metric objects in a VMD. In some cases a VMD may contain a single Channel and that Channel may be functionally superfluous. This may be likely if the attribution of the Channel object consists only of the mandatory *type* and *handle* attributes. In this case it is recommended that the value for the *type* attribute be initialized using the values corresponding to the term having the reference ID MDC DEV CHAN, which is defined in IEEE11073:10101. Usage of this term in this context may provide an indication that the Channel object in question may not require representation in other messaging formats (e.g. IHE PCD-01).

5.3.5 Metric class

The Metric ~~class object~~ is the abstract base class for all classes ~~objects~~ representing direct and derived, quantitative and qualitative biosignal measurement, status, and context data.

Specializations of the Metric ~~class object~~ are provided to deal with common representations (e.g., single values, array data, status indications) and presentations (e.g., on a display) of measurement data.

~~As a base class,~~ The Metric class is abstract and ~~object~~ cannot be instantiated.

5.3.6 Numeric class ~~object~~

The Numeric class models ~~object represents~~ numerical measurements and status information, e.g., amplitude measures, counters.

Example: A heart rate measurement is represented by a Numeric object.

NOTE—A compound Numeric object is defined as an efficient model, for example, for arterial blood pressure, which usually has three associated values (i.e., systolic, diastolic, mean). The availability of multiple values in a single Numeric (or other Metric) object can be indicated in a special structure attribute of ~~in~~ the Metric class ~~object~~.

5.3.7 SampleArray class ~~object~~

The Sample Array ~~class object~~ is the abstract base class for metrics that have a graphical, curve type presentation and, therefore, have their observation values reported as arrays of data points by communicating systems.

The SampleArray ~~As a base class~~ is abstract and ~~, the Sample Array object~~ cannot be instantiated.

5.3.8 Real Time Sample Array class ~~object~~

The RealTimeSampleArray class models ~~object is a sample array that represents~~ a real-time continuous waveform. As such, it has special requirements in communicating systems, e.g., processing power, low latency, high bandwidth. ~~Therefore, it requires the definition of a specialized object.~~

Example: An electrocardiogram (ECG) real-time wave is represented as a RealTimeSampleArray object.

5.3.9 TimeSampleArray class ~~object~~

The TimeSampleArray class models ~~object is a sample array that represents~~ noncontinuous waveforms (i.e., a wave snippet). Within a single observation (i.e., a single array of sample values), samples are equidistant in time.

Example: Software for ST segment analysis may use the TimeSampleArray class ~~object~~ to represent snippets of ECG real-time waves that contain only a single QRS complex. Within this wave snippet, the software can locate the ST measurement points. It generates a new snippet, for example, every 15 s.

5.3.10 DistributionSampleArray class ~~object~~

The DistributionSampleArray class models ~~object is a sample array that represents~~ linear value distributions in the form of arrays containing scaled sample values. Each ~~The index of a~~ value within an observation array represents ~~denotes~~ a measured ~~spatial~~ value from a different point in the parameter space. The DistributionSampleArray shall not be used for measurements distributed in a time ~~point~~.

Example: An electroencephalogram (EEG) application may use a Fourier transformation to derive a frequency distribution (i.e., a spectrum) from the EEG signal. It then uses a ~~the~~ DistributionSampleArray object to represent that spectrum in the MDIB.

5.3.11 Enumeration ~~class~~ ~~object~~

The Enumeration ~~class models~~ ~~object represents~~ status information and/or annotation information. Observation values may be presented in the form of normative codes (that are included in the nomenclature defined in [IEEE 11073 part 10101](#) ~~this standard~~ or in some other nomenclature scheme), [bit string](#), or in the form of free text.

Example: An ECG rhythm qualification may be represented as an Enumeration object. A ventilator may provide information about its current ventilation mode as an Enumeration object.

5.3.12 ComplexMetric ~~class~~ ~~object~~

In special cases, ~~a the~~ ComplexMetric object can be used to group a larger number of strongly related Metric objects in one single container object for performance or for modeling convenience. ~~A~~ ~~The~~ ComplexMetric object is a composition of Metric objects, possibly recursive.

Example: A ventilator device may provide extensive breath analysis capabilities. For each breath, it calculates various numerical values (e.g., volumes, I:E ratio, timing information) as well as enumerated information (e.g., breath type classification, annotation data). For efficiency, all this information is grouped together in one ComplexMetric object instance, which is updated upon each breath.

5.3.13 PM-Store (i.e., persistent metric) ~~class~~ ~~object~~

The PM-Store ~~class~~ ~~object~~ provides long-term storage capabilities for metric data. ~~A PM-Store~~ ~~it~~ contains a variable number of PM-Segment objects that can be accessed only through the PM-Store object. ~~A Without further specialization, the~~ PM-Store object is intended to store data of a single Metric object only.

Example: A device stores the numerical value of an invasive blood pressure on a disk. It uses the PM-Store object to represent this persistent information. The attributes of the PM-Store object describe the sampling period, the sampling algorithm, and the storage format. When the label of the pressure measurement is changed (e.g., during a wedge procedure), the storage process opens a new PM-Segment to store the updated context data (here: the label).

5.3.14 PM-Segment class ~~object~~

The PM-Segment class models ~~object represents~~ a continuous time period in which a metric is stored without any changes of relevant metric context attributes (e.g., scales, labels).

~~The~~ PM-Segment objects are ~~object is~~ accessible only through the PM-Store object that contains them (e.g., for retrieving stored data, the PM-Store object has to be accessed).

5.4 Model for the Alert Package

5.4.1 General

The Alert Package deals with classes ~~objects~~ that represent status information about patient condition and/or technical conditions influencing the measurement or device functioning. Alert-related information is often subject to normative regulations to which a device may be required to comply and, therefore, requires special consideration that is outside the scope of this standard handling.

In the model, all alarm-related object-oriented items are identified by the term alert. The term alert is used in this standard as a synonym for the combination of patient-related physiological alarms, technical alarms, and equipment user-advisory signals.

An alarm is a signal that indicates abnormal events occurring to the patient or the device system. A physiological alarm is a signal that either indicates that a monitored physiological parameter is out of specified limits or indicates an abnormal patient condition. A technical alarm is a signal that indicates a device system is either not capable of accurately monitoring the patient's condition or no longer monitoring the patient's condition.

The model defines three different levels of alarming. These levels represent different sets of alarm processing steps, ranging from a simple context-free alarm event detection to an intelligent device system alarm process. This process facilitates the prioritization of ~~is required to prioritize~~ all device alarms, the latching of ~~to latch~~ alarms if needed (a latched alarm does not stop when the alert ~~alarm~~ condition goes away), and the production of ~~to produce~~ audible and visual alarm indications for the user.

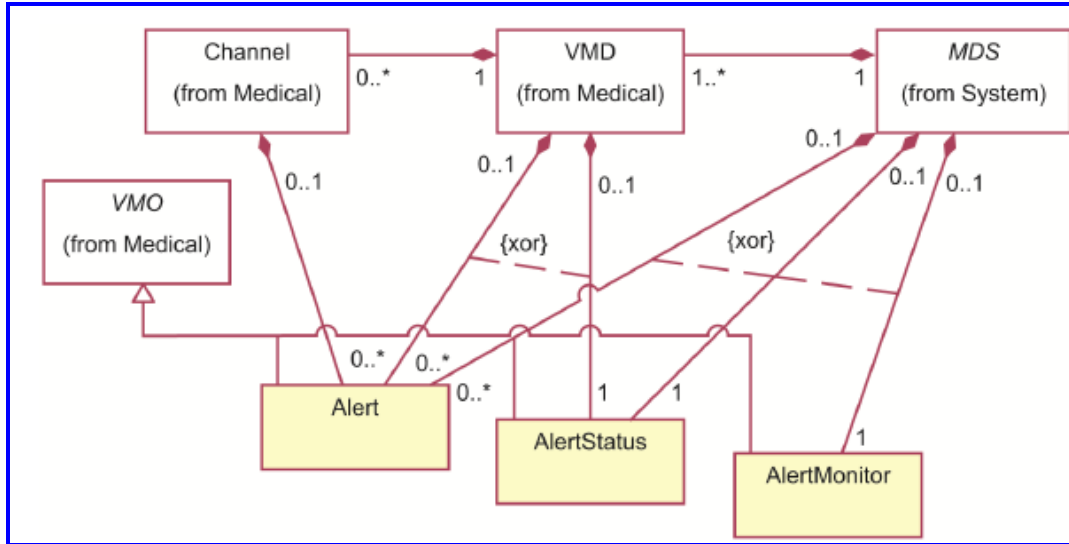
For consistent system-wide alarming, a particular medical device may provide either no alarming capability or exactly one level of alarming, which is dependent on the capabilities of the device. Each level is represented by one specific object class. In other words, either zero or one alarm object class (e.g., only Alert or only AlertStatus or only AlertMonitor; no combinations) is instantiated in the device containment tree. Multiple instances of a class are allowed.

NOTE—Medical device alarming is subject to various national and international safety standards (e.g., IEC 60601 series, ISO 9703 series). Considering requirements of current safety standards, objects in this standard define information contents only. Any implementation shall, therefore, follow appropriate standards for dynamic alarming behavior.

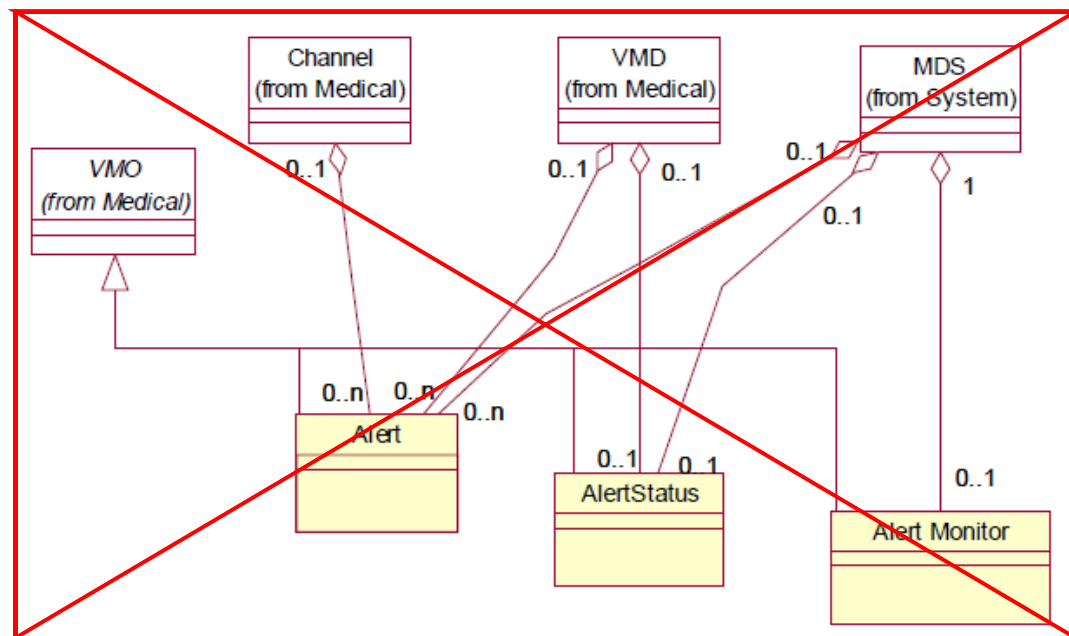
Figure 6-5 shows the UML class diagram for ~~object model of~~ the Alert Package.

NOTE—Instances of classes ~~objects~~ in the Alert Package area shall be contained in exactly one superior object.

The Alert Package model contains the classes ~~objects~~ described in 56.4. 21 through 56.4. 4.3.



(New)



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Figure 6—Alert Package model

5.4.2 Alert ~~class~~ ~~object~~

The Alert ~~class models~~ ~~object stands for~~ the status of a simple ~~alert alarm~~ condition check. As such, ~~an instance~~ ~~it~~ represents a single alarm only. The alarm can be either a physiological alarm or a technical alarm condition of a related object [e.g., MDS ~~(i.e., medical device system)~~, VMD, Metric]. ~~In If a device instantiates an Alert object, it shall not instantiate~~ the ~~case that neither an~~ AlertStatus ~~nor or the~~ AlertMonitor object ~~is used~~, a single Alert object is needed for each ~~alert alarm~~ condition that the device is able to detect.

~~Each~~ ~~The~~ Alert object has a reference to an object ~~defined~~ ~~instance~~ in the Medical Package to which the ~~alert alarm~~ condition relates.

NOTE—An Alert object ~~instance~~ is not dynamically created or deleted in cases where ~~alert alarm~~ conditions start or stop. Rather, an existing Alert ~~object's~~ ~~object instance changes~~ attribute values ~~change (are updated)~~ in these cases.

Example: An Alert object may represent the status of a process that checks for a limit violation physiological alarm of the heart rate signal. In the case of a violation of the limit, the object generates an event (i.e., attribute update) that represents this ~~alert alarm~~ condition in the form of attribute value changes.

5.4.3 AlertStatus ~~class~~ ~~object~~

The AlertStatus ~~class models~~ ~~object represents~~ the output of ~~a an alarm~~ process that considers all ~~alert alarm~~ conditions in a scope that spans one or more objects. In contrast to ~~an the~~ Alert object, ~~the~~ ~~an~~ AlertStatus object collects all ~~alert alarm~~ conditions related to a VMD object hierarchy or related to an MDS object and provides this information in list-structured attributes. Collecting all alarms together allows the implementation of first-level alarm processing where knowledge about the VMD or MDS can be used to prioritize ~~alert alarm~~ conditions and to suppress known false alarm indications.

For larger scale devices without complete alarm processing, ~~use of an the~~ AlertStatus object greatly reduces the overhead of a large number of Alert object instances.

If a device ~~contains~~ ~~instantiates~~ an AlertStatus object, it shall not ~~contain any~~ ~~instantiate the~~ Alert or the AlertMonitor ~~objects~~ ~~object~~. Each VMD or MDS in the MDIB is able to contain at most one ~~Alert Status object~~ instance ~~of the AlertStatus class~~.

Example: An ECG VMD derives a heart rate value. As the VMD is able to detect that the ECG leads are disconnected from the patient, its AlertStatus object reports only a technical alarm and suppresses a heart rate limit violation alarm in this case.

5.4.4 AlertMonitor ~~class~~ ~~object~~

The AlertMonitor ~~class models~~ ~~object represents~~ the output of a ~~medical~~ device ~~or system~~ ~~alert~~ ~~alarm~~ processor. As such, it represents the overall device or system ~~alert~~ ~~alarm~~ condition and provides a list of all ~~alert~~ ~~alarm~~ conditions of the system in its scope. This list includes global state information and individual alarm state information that allows the implementation of a safety-standard-compliant alarm display on a remote system.

If a device ~~contains~~ ~~instantiates~~ an AlertMonitor object, it shall not ~~contain any~~ ~~instantiate the~~ Alert or ~~the~~ AlertStatus ~~objects~~ ~~object~~. An MDS shall ~~contain~~ not ~~contain~~ more than one AlertMonitor object ~~instance~~.

Example: A patient-monitoring system provides ~~alert~~ ~~alarm~~ information in the form of an AlertMonitor object to a central station. Alert information includes the current global maximum severity of audible and visual ~~alert~~ ~~alarm~~ conditions on the monitor display as well as a list of active technical and physiological alarm conditions. The ~~alert~~ ~~alarm~~ processor operates in a latching mode where physiological alarm conditions are buffered until they are explicitly acknowledged by a user.

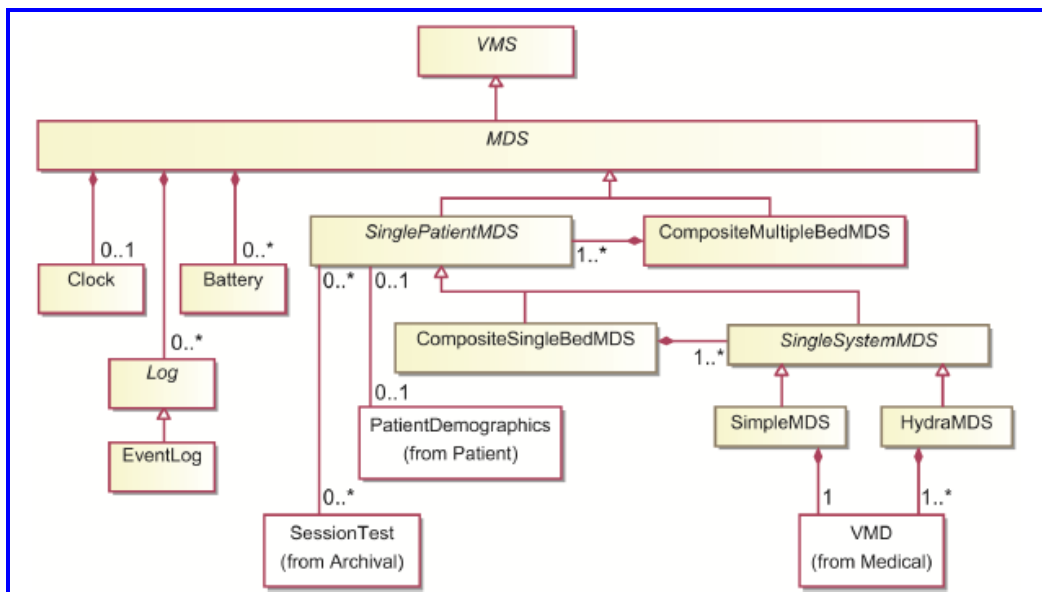
5.5 Model for the System Package

5.5.1 General

The System Package deals with the representation of devices that derive or process vital signs information and comply with the definitions in this standard.

Figure 7 6.6 shows the [UML class diagram](#) ~~object model~~ for the System Package.

The System Package model contains the [classes](#) ~~objects~~ described in ~~6.5.5.2 1~~ through [5.5.13](#). ~~6.5.10.~~



(New)

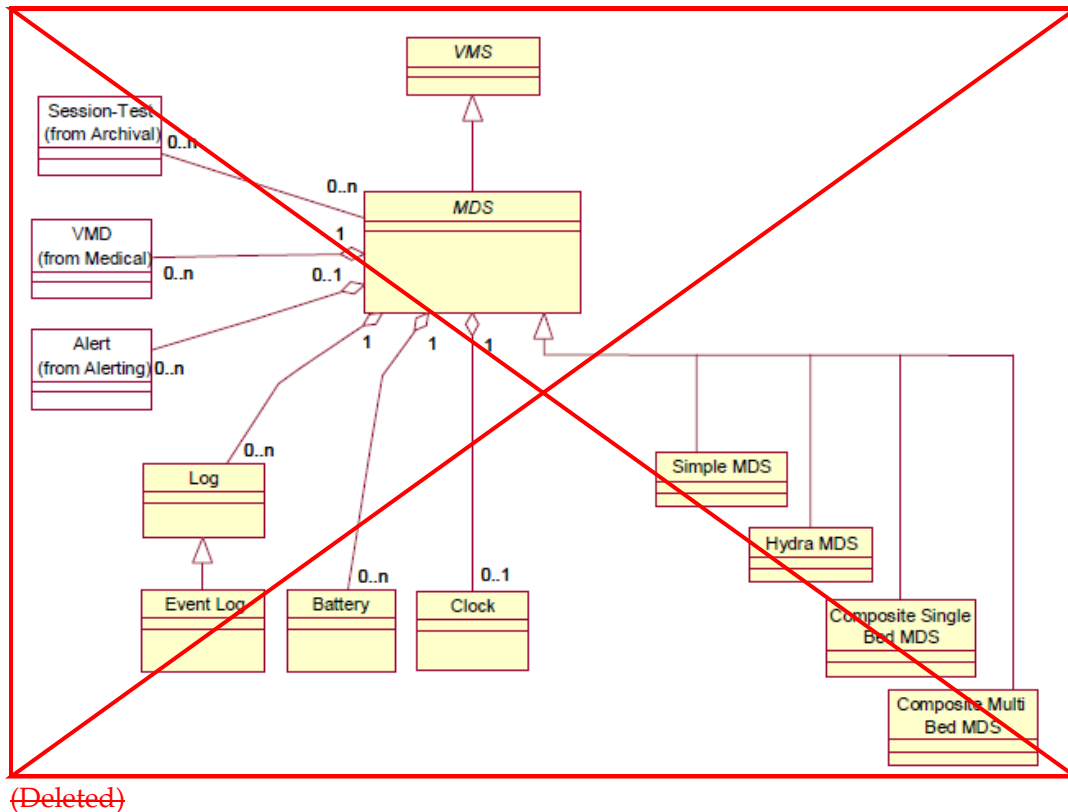


Figure 7—System Package model

5.5.2 VMS (~~i.e.,~~ virtual medical system) ~~class~~ ~~object~~

The VMS ~~class~~ ~~object~~ is the abstract base class for all System Package ~~classes~~ ~~objects~~ in this model. It provides ~~consistent~~ ~~consistent~~ naming and identification of system-related objects.

~~The VMS~~ ~~As a base~~ ~~class~~ ~~is abstract and~~ ~~, the VMS object~~ cannot be instantiated.

5.5.3 MDS ~~class~~ ~~object~~

The MDS ~~class~~ ~~object~~ is an abstraction of a device that provides medical information in the form of ~~instances of classes~~ ~~objects~~ that are defined in the Medical Package of the DIM.

~~An instance of~~ the MDS ~~class~~ ~~object~~ is the top-level object in the device's MDIB and represents the instrument itself. Composite devices may contain additional MDS objects in the MDIB.

Further specializations of this class are used to represent differences in complexity and scope.

The MDS ~~As a base~~-class is abstract and ~~,the MDS object~~ cannot be instantiated.

5.5.4 CompositeMultipleBedMDS class

The CompositeMultipleBedMDS class models a device that contains multiple MDS objects at multiple locations (i.e., multiple beds).

5.5.5 SinglePatientMDS class

The SinglePatientMDS is an abstract class that models a medical device that is associated with a single patient.

The SinglePatientMDS class is abstract and cannot be instantiated.

5.5.6 CompositeSingleBedMDS class

The CompositeSingleBedMDS class models a device that contains one or more SimpleMDS or HydraMDS objects at one location (i.e., a bed).

5.5.7 SingleSystemMDS class

The SingleSystemMDS class models a medical device that contains VMD objects and that may be contained by a CompositeMDS object.

The SingleSystemMDS class is abstract and cannot be instantiated.

5.5.8 SimpleMDS class ~~object~~

The SimpleMDS class models ~~object represents~~ a medical device that contains a single VMD instance only (i.e., a single-purpose device).

5.5.9 HydraMDS class ~~object~~

The HydraMDS class models ~~Hydra MDS object represents~~ a device that contains multiple VMD instances (i.e., a multipurpose device).

~~6.5.5 Composite Single Bed MDS object~~

~~The Composite Single Bed MDS object represents a device that contains (or interfaces with) one or more Simple or Hydra MDS objects at one location (i.e., a bed).~~

~~6.5.6 Composite Multiple Bed MDS object~~

~~The Composite Multiple Bed MDS object represents a device that contains (or interfaces with) multiple MDS objects at multiple locations (i.e., multiple beds).~~

5.5.10 Log class ~~object~~

The Log class ~~object~~ is an abstract a base class that models ~~is~~ a storage container for important local system notifications and events. It is possible to define specialized classes for specific event types.

The Log ~~As a base class is abstract and~~ ~~, the Log object~~ cannot be instantiated.

5.5.11 EventLog class ~~object~~

The EventLog class models ~~object is~~ a general Log object that stores system events in a free-text representation.

Example: An infusion device may want to keep track of mode and rate changes by remote systems. When a remote operation is invoked, it creates an entry in its event log.