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**Medizinische Informatik –
Geräteinteroperabilität –
Teil 10201: Kommunikation patientennaher medizinischer Geräte –
Bereichs-Informationsmodell (ISO/IEEE 11073-10201:2020);
Englische Fassung EN ISO 11073-10201:2020**

Health informatics –
Device interoperability –
Part 10201: Point-of-care medical device communication – Domain information model
(ISO/IEEE 11073-10201:2020);
English version EN ISO 11073-10201:2020

Informatique de santé –
Interopérabilité des dispositifs –
Partie 10201: Communication entre dispositifs médicaux sur le site des soins – Modèle
d'informations du domaine (ISO/IEEE 11073-10201:2020);
Version anglaise EN ISO 11073-10201:2020

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Nationales Vorwort

Dieses Dokument (EN ISO/IEEE 11073-10201:2020) wurde vom Technischen Komitee ISO/TC 215 „Health informatics“ in Zusammenarbeit mit dem IEEE „Institute of Electrical and Electronics Engineers“ und in Zusammenarbeit mit dem Technischen Komitee CEN/TC 251 „Medizinische Informatik“, dessen Sekretariat von NEN (Niederlande) gehalten wird, erarbeitet.

Der Arbeitsausschuss NA 063-07-02 AA „Interoperabilität“ des Fachbereichs 7 „Medizinische Informatik“ des DIN-Normenausschusses Medizin (NAMED) hat an der Erarbeitung mitgewirkt.

Dieses Dokument enthält unter Berücksichtigung des Präsidialbeschlusses 1/2004 nur die Englische Fassung von EN ISO 11073-10201:2020 und ISO/IEEE 11073-10201:2020.

Für die in diesem Dokument zitierten Dokumente wird im Folgenden auf die entsprechenden deutschen Dokumente hingewiesen:

ISO 3166-1	Siehe	DIN EN ISO 3166-1
ISO 3166-3	Siehe	DIN ISO 3166-3
ISO 8601	Siehe	DIN ISO 8601
ISO 12052	Siehe	DIN EN ISO 12052
ISO 15225	Siehe	DIN EN ISO 15225
ISO/IEC 2022	Siehe	DIN ISO/IEC 2022
ISO/IEC 7498-1	Siehe	DIN EN ISO/IEC 7498-1
ISO/IEC 9545	Siehe	DIN ISO/IEC 9545
ISO/IEEE 11073-10101	Siehe	DIN EN ISO 11073-10101
ISO/IEEE 11073-20101	Siehe	DIN EN ISO 11073-20101
ISO/IEEE 11073-20601	Siehe	DIN EN ISO 11073-20601

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Zusammenfassung

Der Anwendungsbereich dieses Projekts ist die Festlegung eines allgemeinen objektorientierten Informationsmodells, das zur Strukturierung von Informationen und Identifikation von Diensten und Kommunikation patientennaher medizinischer Geräte verwendet werden darf. Der Anwendungsbereich konzentriert sich vor allem auf medizinische Geräte für die akute Versorgung und die Kommunikation von Informationen zu Vitalparametern.

Änderungen

Gegenüber DIN EN ISO 11073-10201:2006-11 wurden folgende Änderungen vorgenommen:

- a) die Sprache des Dokuments wurde überarbeitet, um eine klarere Unterscheidung zwischen Domänenmodell-Klassifikatoren und Instanzen von Klassifikatoren zu ermöglichen. Diese Sprache spiegelt die Verwendung der class, object, und instance in zeitgemäßen objektorientierten Methoden wider;
- b) die Definitionen wurden verbessert;
- c) Mehrdeutigkeiten und Inkonsistenzen in dem UML-Model wurden behoben, z. B. wurde klargestellt, dass metrische Objekte (Metric objects) in Kanalobjekten (Channel objects) enthalten sein müssen;
- d) neue abstrakte MDS-Typen wurden hinzugefügt, um die Containmentbeziehungen zwischen den konkreten MDS-Klassen, der VMD-Klasse, der PatientDemographics-Klasse und den Klassen im Archival-Paket genauer auszudrücken;
- e) das UML-Model und der Begleittext wurde überarbeitet;
- f) die VMD-Klasse wurde erweitert, um UDI (Eindeutige Geräte Identifikation, en: Unique Device Identification) zu unterstützen. Elemente der UDI werden zwischen den Datentypen ProductionSpec und UdiSpec aufgeteilt;
- g) die Verweisungen wurden aktualisiert;
- h) der Text wurde redaktionell überarbeitet.

Frühere Ausgaben

DIN EN ISO 11073-10201: 2006-11

Nationaler Anhang NA (informativ)

Begriffe

Reihenfolge und Inhalt der folgenden Begriffe sind identisch mit denen im Abschnitt Begriffe der Englischen Fassung.

3 Begriffe, Akronyme und Abkürzungen

Für die Anwendung dieses Dokuments gelten die folgenden Begriffe. Das IEEE Standards Dictionary Online sollte für Begriffe, die in diesem Abschnitt nicht definiert werden, zurate gezogen werden.¹

3.1 Begriffe

Agent

(en: agent)

Gerät, das Daten in einem Manager/Agent-Kommunikationssystem bereitstellt

Alarm

(en: alarm)

Signal, das abnormale Ereignisse anzeigt, die beim Patienten oder dem Gerätesystem auftreten

Warnung

(en: alert)

Synonym für die Kombination aus patientenbezogenen physiologischen Alarmen, technischen Alarmen und Warnsignalen für die Nutzer von Ausrüstung

Warnzustand

(en: alert condition)

aktiver Zustand (wahr) eines physiologischen Alarms (primär in Bezug auf den Patienten), technischen Alarms (primär in Bezug auf das Gerät) oder eines Hinweises, der üblicherweise Medizinern, Ärzten oder anderen Mitarbeitern der medizinischen Versorgung zur Reaktion auf Patientenbedürfnisse oder entsprechende Arbeitsabläufen gegeben wird

Warnungsmonitor

(en: alert monitor)

Objekt, das das Ergebnis eines Warnsystems darstellt, das verschiedene Warnzustände in einem durch Objekte festgelegten Anwendungsbereich berücksichtigt, die in einem einzelnen Medizingerätesystemobjekt enthalten sind, und das einzelne gleichzeitige Warnzustände sowie den Gesamtwarnzustand anzeigen kann

1 Das *IEEE Standards Dictionary Online* ist verfügbar unter <http://dictionary.ieee.org/>. Für den Zugriff auf das Wörterbuch ist ein IEEE-Konto erforderlich. Dieses kann kostenlos auf der Anmeldungsseite erstellt werden.

Warnstatus

(en: alert status)

Objekt, das das Ergebnis eines Warnsystems darstellt, das verschiedene Warnzustände in einem durch Objekte festgelegten Anwendungsbereich berücksichtigt, die entweder in einem einzelnen virtuellen Medizingeräteobjekt oder in einem einzelnen Medizingerätesystemobjekt enthalten sind, und das gleichzeitige Warnzustände angeben kann

archivisch

(en: archival)

mit Bezug auf die Datenspeicherung über einen längeren Zeitraum

Assoziationssteuerungsdienstelement

(en: association control service element, ACSE)

Verfahren zur Einrichtung logischer Verbindungen zwischen den Medizingerätesystemen

Attribut

(en: attribute)

Definition einer Eigenschaft eines Objekts

Kanal

(en: channel)

Objekt, das physiologische Messdaten und alle abgeleiteten Daten mit einer kontextuellen Beziehung zueinander gruppiert

Klasse

(en: class)

Modell, das die Eigenschaften und Verhaltensweisen eines Entitätstyps innerhalb eines Problembereichs beschreibt

Klassendiagramm

(en: class diagram)

Diagramm, das die Verbindungen zwischen Klassen in einem System beschreibt

Kommunikationssteuerung

(en: communication controller)

Teil eines Medizingerätesystems, das für Kommunikation verantwortlich ist

Kommunikationspartei

(en: communication party)

Akteur eines Problembereichs, der an der Kommunikation in diesem Bereich teilnimmt

Kommunikationsfunktion

(en: communication role)

Funktion einer Partei in einer Kommunikationssituation, die das Verhalten der Partei in der Kommunikation festlegt, und mit der eine Dienstmenge verbunden wird, die die Partei anderen Parteien zur Verfügung stellt

Datenagent

(en: data agent)

Patientendatenerfassungssystem bei medizinischen Geräten, das die erfassten Daten für andere Geräte bereitstellt

Datenformat

(en: data format)

Anordnung von Daten in einer Datei oder einem Strom

Datenlogger

(en: data logger)

Gerät, das in seiner Kapazität als Datenspeicherungs- und archivisches System funktioniert

ANMERKUNG Es können mehrere unterschiedliche Datenloggertypen vorkommen; klinische, technische, forensische, Alarmzustände, Benutzerlogs.²

Datenstruktur

(en data structure)

durch eine Anwendung implementiertes Datenorganisationsformat

Verzeichnis

(en: dictionary)

Beschreibung der Inhalte der Informationsdatenbank für medizinische Daten (en: medical data information base, MDIB) mit Informationen zu Vitalparametern, Geräteinformationen, demographischen Daten und anderen Elementen der MDIB

diskreter Parameter

(en: discrete parameter)

gemessener, berechneter oder manuell eingegebener Wert, der als einzelner numerischer oder textlicher Wert angegeben werden kann

BEISPIEL Ein nichtinvasiver systolischer Blutdruck (gemessen), Herzindex (berechnet), männliches oder weibliches Geschlecht.

Domäneninformationsmodell

(en: domain information model, DIM)

Modell zur Beschreibung allgemeiner Begriffe und Beziehungen für einen Problembereich

Ereignis

(en: event)

Änderung im Gerätestatus, der durch einen Benachrichtigungsmittelungsdienst kommuniziert wird

² Anmerkungen in Texten, Tabellen und Bildern einer Norm werden lediglich zu Informationszwecken angegeben und enthalten keine Anforderungen, die zur Umsetzung dieser Norm erforderlich sind.

Ereignisbericht

(en: event report)

(durch ein allgemeines Informationsdienstelement für Medizinprodukte bereitgestellter) Dienst zur Mitteilung eines Ereignisses mit Bezug zu einer verwalteten Objektinstanz

Rahmenwerk

(en: framework)

Struktur von Prozessen und Spezifikationen, die zur Unterstützung der Erfüllung einer bestimmten Aufgabe entwickelt wurde

Graphikparameter

(en: graphic parameter)

Parameter, der verschiedene regelmäßig abgefragte Datenpunkte erfordert, um ordnungsgemäß ausgedrückt zu werden

BEISPIEL Ein einzelner Ausschnitt der Wellenform eines Elektrokardiogramms.

Host-System

als Abstraktion eines medizinischen Systems verwendeter Begriff, mit dem Messgeräte verbunden sind

Informationsdienstelement

(en: information service element)

Instanzen in der Informationsdatenbank für medizinische Daten

Instanz

(en: instance)

Realisierung eines abstrakten Konzepts oder einer Spezifikation, z. B. Klasseninstanz, Anwendungsinstanz, Informationsdienstelementinstanz, Instanz für virtuelle medizinische Geräte, Betriebsinstanz

Instanzmethode

(en: instance method)

Verfahren oder Prozess, bei dem ein Verhalten festlegt wird, das durch die Instanzen einer Klasse dargestellt wird (d. h. Objekte). Instanzmethoden stellen die Schnittstelle dar, durch die auf die Eigenschaften eines Objekts zugegriffen oder durch die sie geändert werden dürfen

Intensivstation

(en: intensive care unit, ICU)

Station einer medizinischen Einrichtung, in der die Patienten mit verschiedenen Überwachungs- und Therapiemodi behandelt werden

Austauschformat

(en: interchange format)

Darstellung von Datenelementen und der Struktur der Benachrichtigung, die diese Datenelemente bei der Übertragung zwischen Systemen enthält, bestehend aus einem Datensatz mit Konstruktionselementen und einer Syntax, die technologiespezifisch ist

Interoperabilität

(en: interoperability)

Fähigkeit von zwei oder mehreren Geräten oder Systemen, in einem Format, das von den Informationsempfängern nutzbar ist, Informationen auszutauschen

Latenz

(en: latency)

Zeitverzögerung zwischen dem Senden eines Signals von einem Gerät und dessen Empfang von einem anderen Gerät in einem Kommunikationsszenario

untere Schichten

(en: lower layers)

Schicht 1 bis Schicht 4 des Referenzmodells der Internationalen Organisation für Normung (en: International Organization for Standardization, ISO)/Kommunikation Offener Systeme (en: open systems interconnection, OSI), die mechanische, elektrische und allgemeine Kommunikationsprotokollspezifikationen abdecken

Manager

(en: manager)

Gerät, das Daten in einem Manager/Agent-Kommunikationssystem empfängt

Manager/Agent-Modell

(en: manager-agent model)

Kommunikationsmodell, bei dem ein Gerät (d. h. Agent) Daten bereitstellt und ein anderes Gerät (d. h. Manager) Daten empfängt

Informationsdatenbank für medizinische Daten

(en: medical data information base, MDIB)

Konzept einer objektorientierten Datenbank, die (mindestens) Informationen zu Vitalparametern speichert.

medizinisches Gerät

(en: medical device)

Gerät, Apparat oder System, das zur Überwachung, Behandlung oder Therapie von Patienten verwendet wird und üblicherweise nicht in Stoffwechselwege eindringt. Für die Anwendung die Norm ist der Anwendungsbereich von Medizinprodukten weiter begrenzt auf mit Patienten verbundene Medizinprodukte, die Unterstützung für elektronische Kommunikation bereitstellen

Medizingerätesystem

(en: medical device system, MDS)

Abstraktion für ein System mit einem oder mehreren medizinischen Funktionen. Im Rahmen dieser Norm wird der Begriff spezifisch als objektorientierte Abstraktion eines Geräts genutzt, das medizinische Informationen in Form von Instanzen der in dieser Norm festgelegten Klassen angibt

Monitor

(en: monitor)

medizinisches Gerät zur Erfassung, Anzeige, Aufzeichnung und/oder Analyse von Patientendaten und zur Warnung von Pflegekräften bei Ereignissen, die deren Aufmerksamkeit erfordern

Objekt

(en: object)

bestimmte Instanz einer Klasse. Ein Objekt stellt ein physisches oder logisches Auftreten eines tatsächlichen medizinischen Geräts oder einer medizinischen Komponente dar. Syn.: Objektinstanz

Objektinstanz

(en: object instance)

siehe: Objekt

objektorientierte Analyse

(en: object-oriented analysis)

Analyseverfahren, bei dem der Problembereich in Form von Klassen und Beziehungen zwischen diesen Klassen modelliert wird

offenes System

(en: open system)

Reihe von Protokollen, die es Computern ermöglicht, verschiedene Quellen miteinander zu verknüpfen

Operation

(en: operation)

Funktion oder Umwandlung, die auf oder durch andere Objekte angewandt werden darf (manchmal auch Dienst genannt)

Problembereich

(en: problem domain)

der zu berücksichtigende Bereich der medizinischen Versorgung in einem Modellverfahren

Protokoll

(en: protocol)

Normregelsatz zur Beschreibung der Datenübertragung zwischen Geräten, der das Datenformat und die Signale für Beginn, Steuerung und Ende der Übertragung festlegt

Echtzeit

(en: real time)

zum Zeitpunkt, an dem ein Ereignis oder ein Verfahren auftritt

Scanner

(en: scanner)

Beobachter und „Zusammenfasser“ von Attributwerten

Szenario

(en: scenario)

formale Beschreibung einer Geschäftstätigkeitsklasse einschließlich der Semantik von Geschäftsvereinbarungen, Übereinkommen und Informationsinhalten

Dienst

(en: service)

bestimmtes Verhalten, für dessen Darstellung eine Kommunikationspartei in einer bestimmten Funktion verantwortlich ist

Syntax (d. h. eines Austauschformats)

(en: syntax)

Regeln zur Kombination von Konstruktionselementen des Austauschformats

System

(en: system)

abgegrenzter Teil eines wahrnehmbaren Universums, das in Zeit und Raum besteht und als Satz von Elementen und Beziehungen zwischen diesen Elementen angesehen werden darf

Zeitstempel

(en: timestamp)

Attribut oder Feld in Daten, das den Zeitpunkt der Datenerstellung festhält

Spitzenklasse

(en: top class)

letzte Basisklasse für die meisten Klassen, die zum in dieser Norm festgelegten Domäneninformationsmodell gehören

obere Schichten

(en: upper layers)

Schicht 5 bis Schicht 7 des Referenzmodells der Internationalen Organisation für Normung (en: International Organization for Standardization, ISO)/Kommunikation Offener Systeme (en: open systems interconnection, OSI), die Anwendung, Darstellung sowie Sitzungsspezifikationen und Funktionalitäten abdecken

virtuelles medizinisches Gerät

(en: virtual medical device, VMD)

abstrakte Darstellung eines medizinbezogenen Untersystems eines Medizingerätesystems

virtuelles medizinisches Objekt

(en: virtual medical object, VMO)

abstrakte Darstellung eines Objekts im Medizinpaket des Domäneninformationsmodells

Vitalparameter

(en: vital sign)

klinische Information mit Bezug auf einen oder mehrere Patienten, die von einem Apparat gemessen oder auf andere Art vom Patienten eingeholt wird

Wellenform

(en: waveform)

Graphikdaten, üblicherweise Vitalparameterdatenwerte, die in Bezug auf Zeit variieren, in der Regel dem Mediziner in graphischer Form dargestellt

3.2 Abkürzungen und Akronyme

ACSE	Assoziationssteuerungsdienstelement (en: association control service element)
ASN.1	Abstrakte Syntax-Notation Eins (en: Abstract Syntax Notation One)
BCC	bettseitige Kommunikationssteuerung (en: bedside communication controller)
BER	grundlegende Codierregeln (en: basic encoding rules)
BMP	mehrsprachige Basisebene (en: basic multilingual plane)
CMDIP	allgemeines Informationsprotokoll für medizinische Geräte (en: Common Medical Device Information Protocol)
CMDISE	allgemeines Informationsdienstelement für medizinische Geräte (en: common medical device information service element)
CMIP	allgemeines Protokoll für Management-Informationen (en: Common Management Information Protocol)
CMISE	allgemeines Verwaltungsinformationsdienstelement (en: common management information service element)
DCC	Gerätekommunikationssteuerung (en: device communication controller)
DICOM	digitale Bildgebung und -kommunikation in der Medizin (en: digital imaging and communications in medicine)
DIM	Domäneninformationsmodell (en: domain information model)
EBWW	Zeiteinstellung mit Auge und Uhr (en: eyeball and wristwatch)
ECG	Elektrokardiogramm (en: electrocardiogram)
EEG	Elektroenzephalogramm (en: electroencephalogram)
FSM	endlicher Automat (en: finite state machine)
GMDN	globale Nomenklatur für Medizinprodukte (en: Global Medical Device Nomenclature)
GMT	mittlere Greenwich-Zeit (en: Greenwich mean time)
IANA	Behörde für die Internetnummernvergabe (en: Internet Assigned Numbers Authority)
ICS	Erklärung zur Konformität der Implementierung (en: implementation conformance statement)
ICU	Intensivstation (en: intensive care unit)
ID	Identifikator oder Identifizierung (en: identifier or identification)
LAN	lokales Netzwerk (en: local area network)
LSB	niedrigstwertiges Bit (en: least significant bit)

MDC	Kommunikation medizinischer Geräte (en: medical device communication)
MDIB	Informationsdatenbank für medizinische Daten (en: medical data information base)
MDS	Medizingerätesystem (en: medical device system)
MEDICOM	medizinische Bildgebungskommunikation (en: medical imaging communication)
MIB oder Mib	Verwaltungsinformationsbasis (en: management information base)
MOC	verwaltete Objektklasse (en: managed object class)
OID	Objektbezeichner (en: object identifier)
OR	Operationssaal (en: operating room)
OSI	Kommunikation offener Systeme (en: open systems interconnection)
PC	Personal-Computer (en: personal computer)
PDU	Protokolldateneinheit (en: protocol data unit)
PM	dauerhafte Metrik (en: persistent metric)
POC	patientennaher Bereich (en: point of care)
SCADA	Aufsichtskontrolle und Datenerfassung (en: supervisory control and data acquisition)
SCP ECG	Standardkommunikationsprotokoll [für computergestützte] Elektrokardiographie (en: Standard Communications Protocol [for computer-assisted] Electrocardiography)
SNMP	einfaches Netzwerkverwaltungsprotokoll (en: Simple Network Management Protocol)
SNTP	einfaches Netzwerkzeitprotokoll (en: Simple Network Time Protocol)
UDI	eindeutiger Identifikator eines Medizinprodukts (en: Unique Device Identification)
UML	vereinheitlichte Modellierungssprache (en: unified modeling language)
UTC	koordinierte Weltzeit (en: coordinated universal time)
VMD	virtuelles medizinisches Gerät (en: virtual medical device)
VMO	virtuelles medizinisches Objekt (en: virtual medical object)
VMS	virtuelles medizinisches System (en: virtual medical system)

Nationaler Anhang NB (informativ)

Literaturhinweise

DIN EN ISO 3166-1, *Codes für die Namen von Ländern und deren Untereinheiten — Teil 1: Codes für Ländernamen*

DIN EN ISO 11073-10101, *Medizinische Informatik — Kommunikation patientennaher medizinischer Geräte — Teil 10101: Nomenklatur*

DIN EN ISO 11073-20101, *Medizinische Informatik — Kommunikation patientennaher medizinischer Geräte — Teil 20101: Anwendungsprofil — Basisnorm*

DIN EN ISO 11073-20601, *Medizinische Informatik — Kommunikation von Geräten für die persönliche Gesundheit — Teil 20601: Anwendungsprofil — Optimierte Datenübertragungsprotokoll*

DIN EN ISO 12052, *Medizinische Informatik — Digitale Bildverarbeitung und Kommunikation in der Medizin (DICOM) inklusive Workflow und Datenmanagement*

DIN EN ISO 15225, *Medizinprodukte — Qualitätsmanagement — Datenstruktur für die Nomenklatur von Medizinprodukten*

DIN EN ISO/IEC 7498-1, *Informationstechnik — Kommunikation Offener Systeme — Teil 1: Basis-Referenzmodell: Basismodell*

DIN ISO 3166-3, *Codes für die Namen von Ländern und deren Untereinheiten — Teil 3: Code für früher gebräuchliche Ländernamen*

DIN ISO 8601, *Datenelemente und Austauschformate — Informationsaustausch — Darstellung von Datum und Uhrzeit*

DIN ISO/IEC 2022, *Informationstechnik — Zeichencodestruktur und Erweiterungstechniken*

DIN ISO/IEC 9545, *Informationstechnik — Kommunikation Offener Systeme — Struktur der Anwendungsschicht**

* DIN ISO/IEC 9545 wurde 2016-05 ohne Ersatz zurückgezogen. ISO/IEC 9545 ist weiterhin gültig.

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English Version

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Bereichs-Informationsmodell
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This European Standard was approved by CEN on 2 May 2020.

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

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European foreword

This document (EN ISO/IEEE 11073-10201:2020) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with Technical Committee CEN/TC 251 "Health informatics" the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2020, and conflicting national standards shall be withdrawn at the latest by December 2020.

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This document supersedes EN ISO 11073-10201:2005.

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Endorsement notice

The text of ISO/IEEE 11073-10201:2020 has been approved by CEN as EN ISO/IEEE 11073-10201:2020 without any modification.

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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IEEE Std 11073-10201™-2018

(Revision of
IEEE Std 11073-10201-2004)

Health informatics—Point-of-care medical device communication

Part 10201: Domain Information Model

Sponsor

IEEE 11073™ Standards Committee
of the
IEEE Engineering in Medicine and Biology Society

Approved 5 December 2018

IEEE-SA Standards Board

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.

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). For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments or corrigenda) applies.

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

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

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/>).

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/>

3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this document, the following terms and definitions apply. The *IEEE Standards Dictionary Online* 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.

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 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 as well as the overall system alert condition.

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

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.

attribute: The definition of a property of an object.

channel: An object that groups together physiological measurement data and any derived 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.

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

communication controller: Part of a medical device system 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.

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.

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

data logger: A 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.

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 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.

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) 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 that requires multiple 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.

information service element: Instances in the medical data information base.

instance: The realization of an abstract concept or specification, e.g., class instance, application instance, information service element instance, virtual medical device 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.

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.

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 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.

object instance: *See:* object.

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

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 (sometimes also called service).

problem domain: 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 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: The ultimate base class for most of the classes belonging to the domain information 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.

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

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
MDC	medical device communication

MDIB	medical data information base
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
POC	point of care
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 can be accessed and manipulated using an object access service protocol.

The domain information model (DIM) defines the overall set of classes 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 which also defines the user scenarios covered by the ISO/IEEE 11073 family of standards.

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, including measurement information, contextual data, device control methods, and other relevant aspects.
- Provide detailed specification of the classes 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, their attributes, and their methods.

⁶ Information on references can be found in Clause 2.

- 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, 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 defined in the information model are considered to model managed (here, medical) objects. For the most part, the objects 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 defined here represent generalized vital signs data and support information. Specialization of these classes is achieved by defining appropriate attributes. Class hierarchies and associations between classes are used to express device configuration and device capabilities.

Example: A generalized object is instantiated to represent vital signs in the form of a real-time waveform. A set of 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 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.

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.

⁷ The numbers in brackets correspond to those of the bibliography in Annex A.

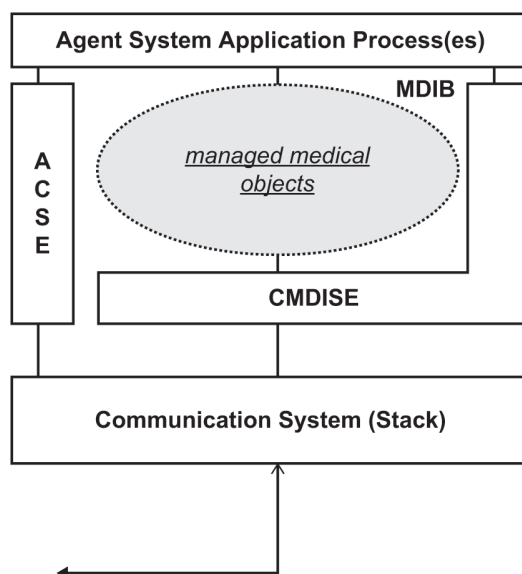


Figure 1—MDIB in communicating systems

Figure 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.

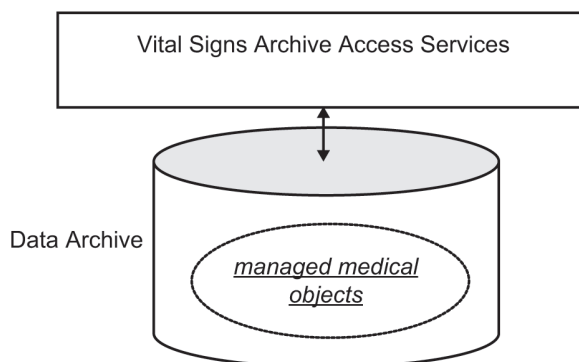


Figure 2—Managed medical objects in a vital signs archive

5.1.2 Scope of the DIM

5.1.2.1 General

Vital signs information classes 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 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) 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 diagrams. Classes are briefly introduced, and their relations and hierarchies are defined in the class diagrams. No single 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 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 generated by objects are also defined in definition tables. These definitions directly relate to the service model specified in Clause 7.

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 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 6.1.3.20).

In other cases, it may be necessary to define completely new classes or to add new attributes, new methods, or new events to already defined classes. 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, 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, 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 inside each package and the relationships between them.

The package diagram depicted in Figure 3 contains only a small subset of all classifiers defined in the DIM. Not all relations are shown between the shown classes. Refer to the detailed UML class diagrams for each package for more information.

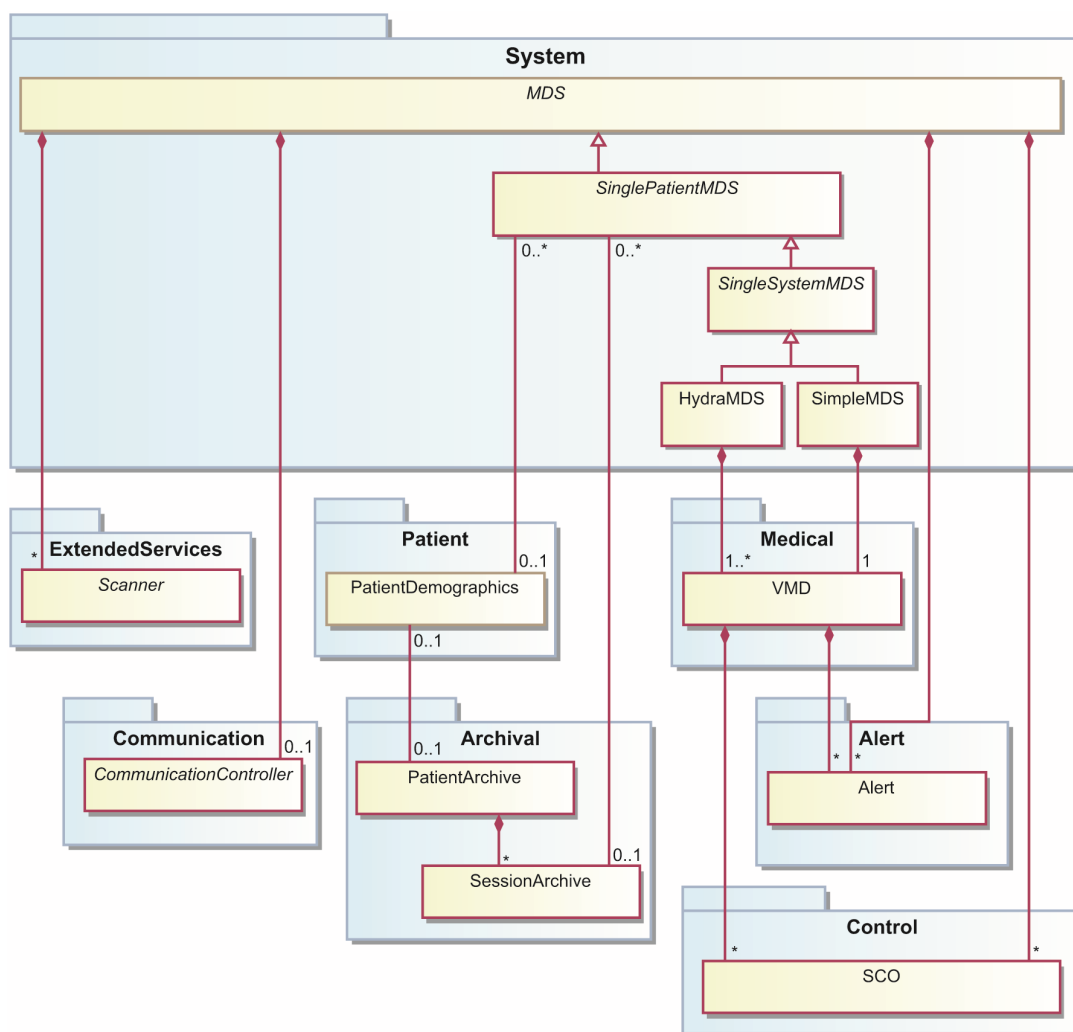


Figure 3—Packages of the DIM

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.

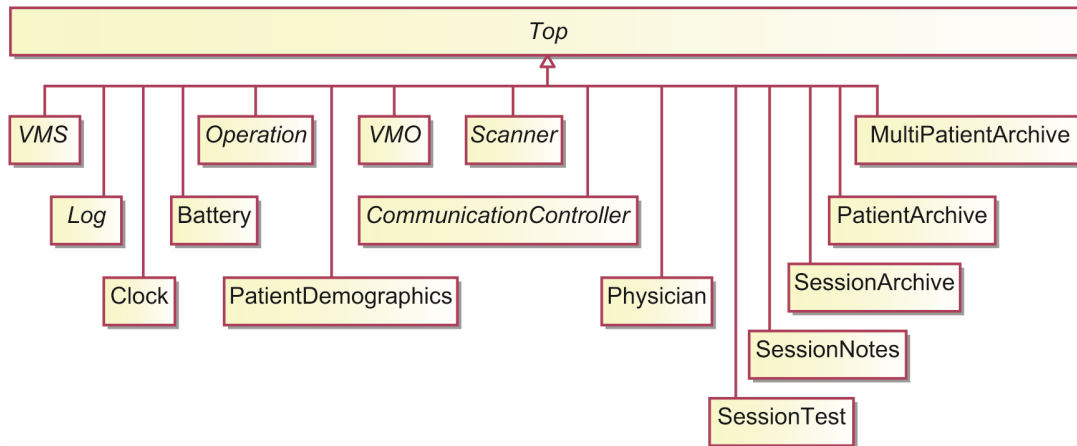


Figure 4—Top class inheritance

The more detailed UML class diagrams for these packages are contained in 5.3 through 5.10. 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 about the class definitions.

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 5 shows the UML class diagram for the Medical Package.

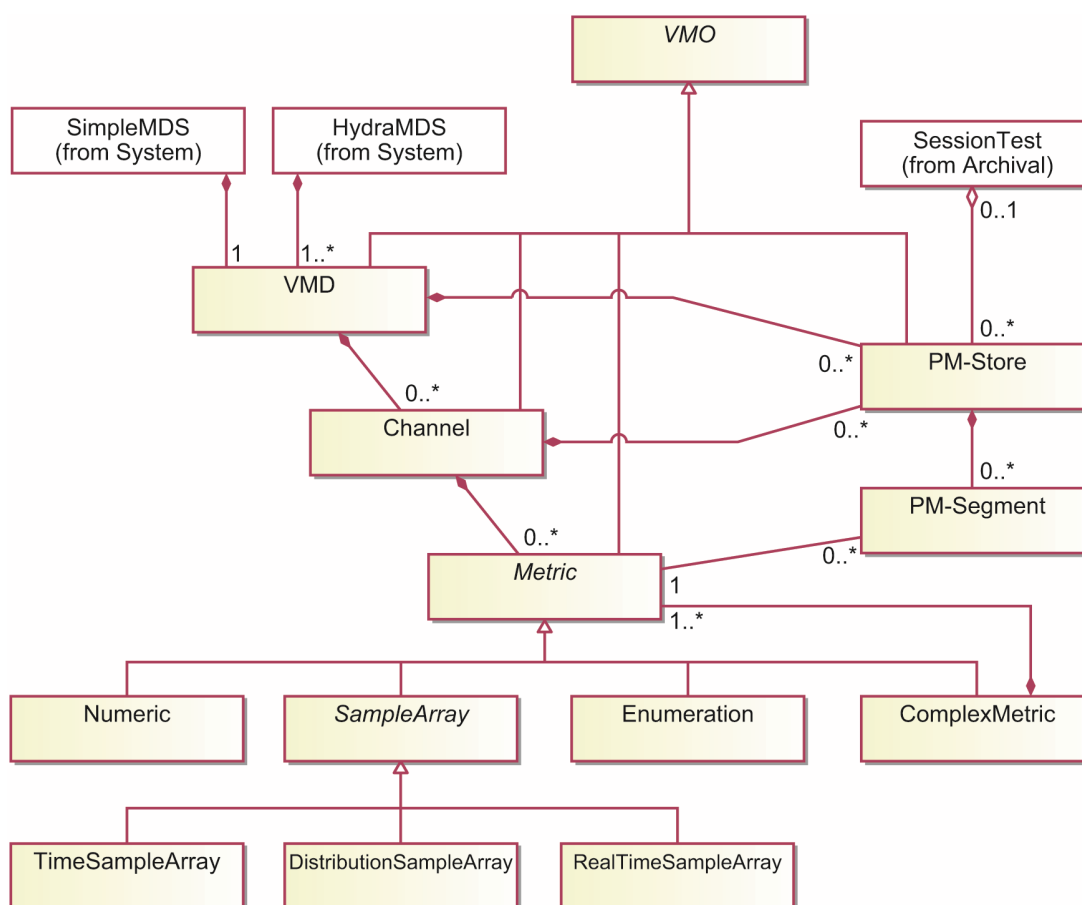


Figure 5—Medical Package model

NOTE—Instances of any class that are modeled with a containment association may be contained by exactly one instance of a container class.

The Medical Package model contains the classes described in 5.3.2 through 5.3.14.

5.3.2 VMO (virtual medical object) class

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

The VMO class is abstract and cannot be instantiated.

5.3.3 VMD (virtual medical device) class

The VMD class models medical-related subsystems (e.g., hardware or even pure software) of medical devices. The characteristics of a subsystem (e.g., modes, versions) are captured by instances of this class. At the same time, a 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

Channel objects are used for grouping Metric objects that have a contextual relationship with each other.

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

Specializations of the Metric class 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.

The Metric class is abstract and cannot be instantiated.

5.3.6 Numeric class

The Numeric class models 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 the Metric class.

5.3.7 SampleArray class

The SampleArray class 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 class is abstract and cannot be instantiated.

5.3.8 RealTimeSampleArray class

The RealTimeSampleArray class models a real-time continuous waveform. As such, it has special requirements in communicating systems, e.g., processing power, low latency, high bandwidth.

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

5.3.9 TimeSampleArray class

The TimeSampleArray class models 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 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

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

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 DistributionSampleArray object to represent that spectrum in the MDIB.

5.3.11 Enumeration class

The Enumeration class models 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 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

In special cases, a 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 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

The PM-Store class provides long-term storage capabilities for metric data. A PM-Store contains a variable number of PM-Segment objects that can be accessed only through the PM-Store object. A 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

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

PM-Segment objects are 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 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.

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 all device alarms, the latching of alarms if needed (a latched alarm does not stop when the alert condition goes away), and the production of 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 shows the UML class diagram for the Alert Package.

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

The Alert Package model contains the classes described in 5.4.2 through 5.4.4.

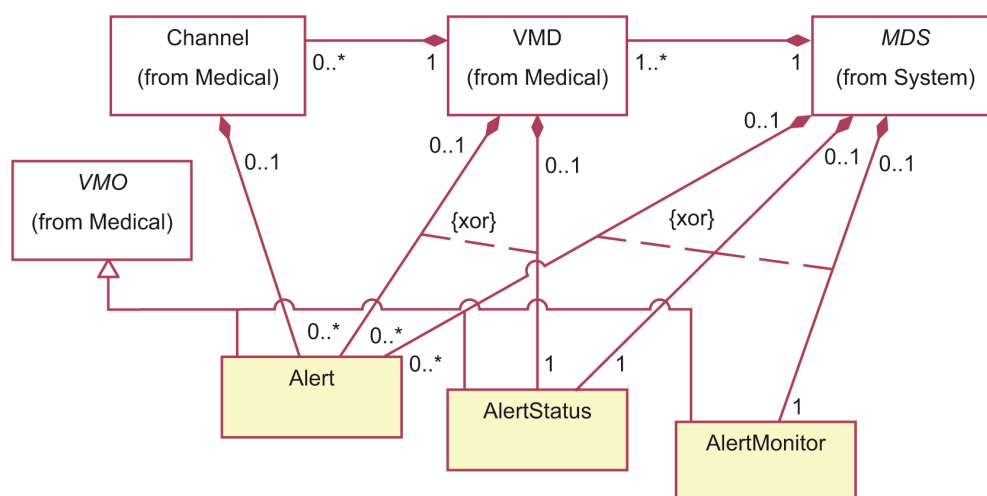


Figure 6—Alert Package model

5.4.2 Alert class

The Alert class models the status of a simple alert condition check. As such, an instance 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, VMD, Metric]. In the case that neither an AlertStatus nor AlertMonitor object is used, a single Alert object is needed for each alert condition that the device is able to detect.

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

NOTE—An Alert object is not dynamically created or deleted in cases where alert conditions start or stop. Rather, an existing Alert object's 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 condition in the form of attribute value changes.

5.4.3 AlertStatus class

The AlertStatus class models the output of a process that considers all alert conditions in a scope that spans one or more objects. In contrast to an Alert object, an AlertStatus object collects all alert 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 conditions and to suppress known false alarm indications.

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

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

The AlertMonitor class models the output of a medical device system alert processor. As such, it represents the overall device or system alert condition and provides a list of all alert 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 an AlertMonitor object, it shall not contain any Alert or AlertStatus objects. An MDS shall not contain more than one AlertMonitor object.

Example: A patient-monitoring system provides alert 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 conditions on the monitor display as well as a list of active technical and physiological alarm conditions. The alert 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 shows the UML class diagram for the System Package.

The System Package model contains the classes described in 5.5.2 through 5.5.13.

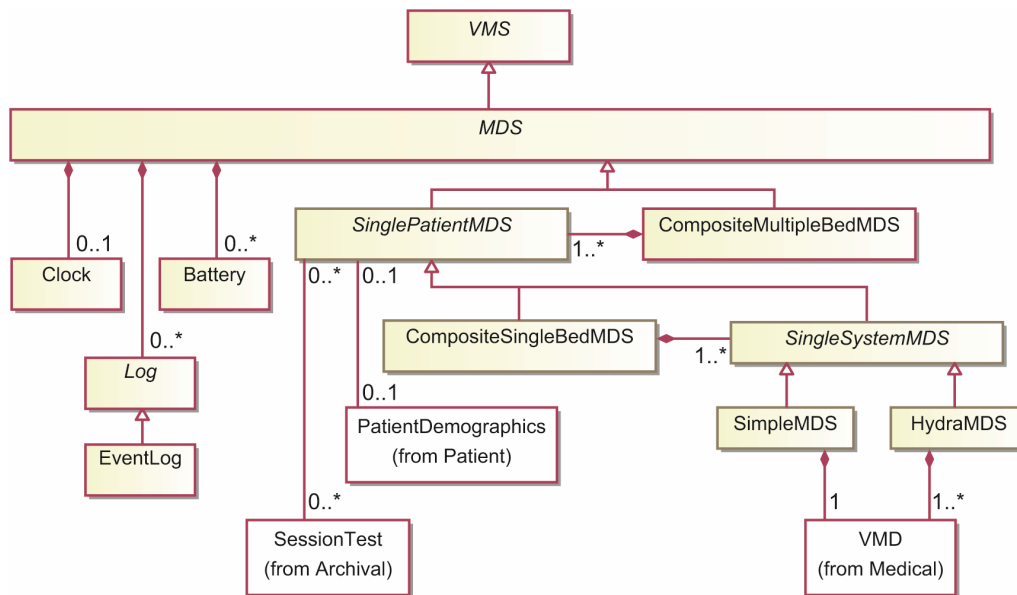


Figure 7—System Package model

5.5.2 VMS (virtual medical system) class

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

The VMS class is abstract and cannot be instantiated.

5.5.3 MDS class

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

An instance of the MDS class 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 class is abstract and 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

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

5.5.9 HydraMDS class

The HydraMDS class models a device that contains multiple VMD instances (i.e., a multipurpose device).

5.5.10 Log class

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

The Log class is abstract and cannot be instantiated.

5.5.11 EventLog class

The EventLog class models 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.

5.5.12 Battery class

For battery-powered devices, some battery information is contained in an MDS object in the form of attributes. If the battery subsystem is either capable of providing more information (i.e., a smart battery) or manageable, then a special Battery object is provided.

5.5.13 Clock class

The Clock class provides additional capabilities for handling date-related and time-related information beyond the basic capabilities of an MDS object. It models the real-time clock capabilities of an MDS object.

The Clock class is used in applications where precise time synchronization of medical devices is needed. This class provides resolution and accuracy information so that applications can synchronize real-time data streams between devices.

5.6 Model for the Control Package

5.6.1 General

The Control Package contains classes that allow remote measurement control and device control.

The model for remote control defined in this standard provides the following benefits:

- A system that allows remote control is able to explicitly register which attributes or features can be accessed or modified by a remote system.
- For attributes that can be remotely modified, a list of possible legal attribute values is provided to the controlling system.
- It is not mandatory that a remote-controllable item correspond to an attribute of a medical object.
- Dependence of a controllable item on internal system states is modeled.
- A simple locking transaction scheme allows the handling of transient states during remote control.

At least two different uses of remote control are considered:

- Automatic control may be done by some processes running on the controlling device. Such a process has to be able to discover automatically how it can modify or access the controllable items to provide its function.
- It is also possible to use remote control to present some form of control interface to a human operator. For this use, descriptions of functions, and possibly help information, need to be provided.

The basic concept presented here is based on Operation objects. An Operation object allows modification of a virtual attribute. This virtual attribute may, for example, be a measurement label, a filter state (on/off), or a gain factor. The attribute is called virtual because it need not correspond to any attribute in other objects instantiated in the system. A virtual attribute may correspond to multiple attributes and may be responsible for a series of actions.

Different specializations of the Operation class define how the virtual attribute is modified. A SelectItemOperation, for example, allows the selection of an item from a given list of possible item values for the attribute. A SetValueOperation allows the setting of the attribute to a value from a defined range with a specific step width (i.e., resolution).

The idea is that the Operation object provides all necessary information about legal attribute values. Furthermore, the Operation object defines various forms of text string to support a human user of the operation. It also contains grouping information that allows logical grouping of multiple Operation objects together when they are presented as part of a human interface.

Operation objects cannot directly be accessed by services defined in the service model in Clause 7. Instead, all controls shall be routed through the SCO (i.e., service and control object). Operation objects support a simple locking mechanism to prevent side effects caused by simultaneous calls.

The SCO groups together all Operation objects that belong to a specific entity (i.e., MDS, VMD). The SCO also allows feedback to a controlled device, for example, for a visual indication that the device is currently remote-controlled.

Figure 8 shows the UML class diagram for the Control Package:

The Control Package model contains the classes described in 5.6.2 through 5.6.10.

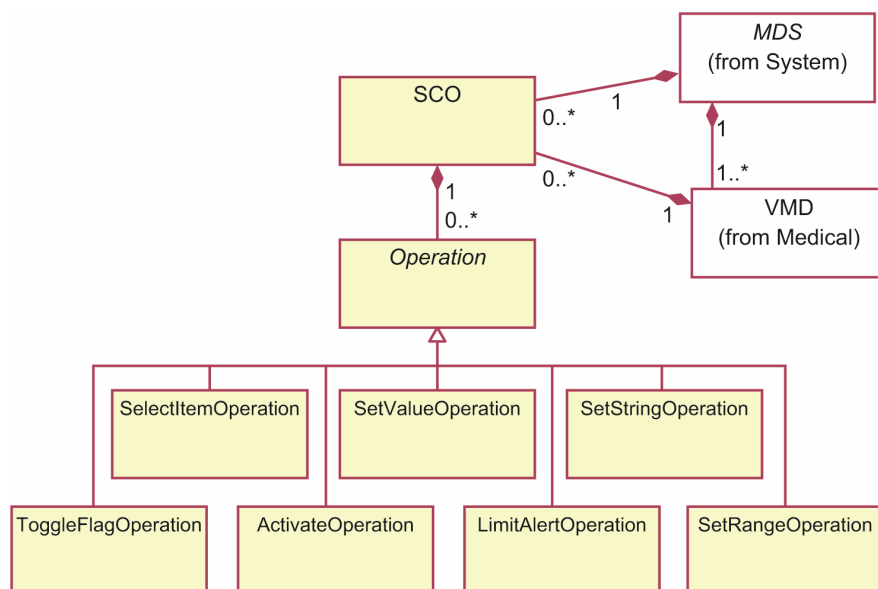


Figure 8—Control Package model

5.6.2 SCO class

An instance of the SCO (service and control object) class is responsible for managing all remote-control capabilities that are supported by a medical device.

Remote control in MDC is sensitive to safety and security issues. The SCO provides means for the following:

- Simple transaction processing, which prevents inconsistencies when a device is controlled from multiple access points (e.g., local and remote) and during the processing of control commands.
- State indications, which allows local and remote indication of ongoing controls.

5.6.3 Operation class

The Operation class is the abstract base class for classes that model remote-controllable items. Each Operation object allows the system to modify some specific item (i.e., a virtual attribute) in a specific way

defined by the Operation object. Operation objects are not directly accessible by services defined in the service model in Clause 7. All controls shall be routed through the SCO object (i.e., the parent) to allow a simple form of transaction processing.

The set of Operation objects instantiated by a particular medical device defines the complete remote control interface of the device. In this way a host system is able to discover the remote control capabilities of a device in the configuration phase.

The Operation class is abstract and cannot be instantiated.

5.6.4 SelectItemOperation class

An instance of the SelectItemOperation class facilitates the selection of one item out of a given list.

Example: The invasive pressure VMD may allow modification of its label. It uses a SelectItemOperation object for this function. The list of legal values supplied by the operation may be, for example, {ABP, PAP, CVP, LAP}. By invoking the operation, a user is able to select one value out of this list.

5.6.5 SetValueOperation class

An instance of the SetValueOperation class facilitates the adjustment of a value within a given range with a given resolution.

Example: A measurement VMD may allow adjustment of a signal gain factor. It uses a SetValueOperation object for this function. The SetValueOperation object provides the supported value range and step width within this range.

5.6.6 SetStringOperation class

An instance of the SetStringOperation class allows the system to set the contents of an opaque string variable of a given maximum length and format.

Example: An infusion device may allow a remote system to set the name of the infused drug in free-text form to show it on a local display. It defines an instance of the SetStringOperation class for this function. The SetStringOperation object specifies the maximum string length and the character format so that the device is able to show the drug name on a small display.

5.6.7 ToggleFlagOperation class

An instance of the ToggleFlagOperation class allows operation of a toggle switch (with two states, e.g., on/off).

Example: An ECG VMD may support a line frequency filter. It uses a ToggleFlagOperation object for switching the filter on or off.

5.6.8 ActivateOperation class

An instance of the ActivateOperation class allows a defined activity to be started (e.g., a zero pressure).

Example: The zero procedure of an invasive pressure VMD may be started with an ActivateOperation object.

5.6.9 LimitAlertOperation class

An instance of the LimitAlertOperation class allows adjustment of the limits of a limit alarm detector and the switching of the limit alarm to on or off.

5.6.10 SetRangeOperation class

An instance of the SetRangeOperation class allows the selection of a value range by the simultaneous adjustment of a low and high value within defined boundaries.

Example: A measurement VMD may provide an analog signal input for which the signal input range can be adjusted with a SetRangeOperation object.

5.7 Model for the ExtendedServices Package

5.7.1 General

The ExtendedServices Package contains classes that provide extended medical object management services that allow efficient access to medical information in communicating systems. Such access is achieved by a set of objects that package attribute data from multiple objects in a single event message.

The classes providing extended services are conceptually derived from ISO/OSI system management services defined in the ISO/IEC 10164 family of standards (specifically Part 5 and Part 13). The definitions have been adapted to and optimized for specific needs in the area of vital signs communication between medical devices.

Figure 9 shows the UML class diagram for the ExtendedServices Package.

The ExtendedServices Package model contains the classes described in 5.7.2 through 5.7.10.

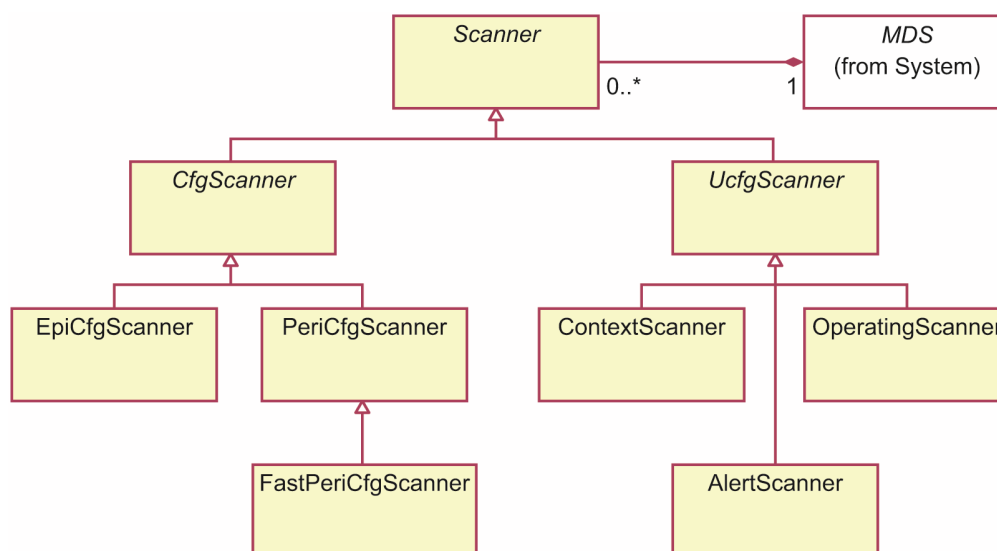


Figure 9—ExtendedServices Package model

5.7.2 Scanner class

The Scanner class is an abstract base class that models an observer and “summarizer” of attribute values. A Scanner object observes attributes of managed medical objects and generates summaries in the form of notification event reports. These event reports contain data from multiple objects, which provide a better communication performance compared to separate polling commands (e.g., GET service) or multiple individual event reports from all object instances.

Subclasses of the Scanner class may be instantiated either by the agent system itself or by the manager system (e.g., dynamic scanner creation by using the CREATE service).

The Scanner class is abstract and cannot be instantiated.

5.7.3 CfgScanner (configurable scanner) class

The CfgScanner class is an abstract base class that defines a special attribute (i.e., the Scan-List attribute) that allows the system to configure attributes of an object are scanned. The Scan-List attribute may be modified either by the agent system (i.e., auto-configuration or pre-configuration) or by the manager system (i.e., full dynamic configuration by using the SET service).

A CfgScanner object may support different granularity for scanning:

- a) Attribute group (i.e., a defined set of attributes): The Scan-List attribute contains the identifiers (IDs) of attribute groups, and all attributes in the group are scanned.
- b) Individual attribute: The Scan-List attribute contains the IDs of all attributes that are scanned.

In order to deal efficiently with optional attributes, the attribute group scan granularity is recommended for CfgScanner objects.

The CfgScanner class is abstract and cannot be instantiated.

5.7.4 EpiCfgScanner (episodic configurable scanner) class

An instance of the EpiCfgScanner class is responsible for observing attributes of managed medical objects and for reporting attribute changes in the form of unbuffered event reports.

The unbuffered event report is triggered only by attribute value changes. If an EpiCfgScanner object uses attribute group scan granularity, the event report contains all attributes of the scanned object that belong to this attribute group if one or more of these attributes changed their value.

Example: A medical device provides heart beat detect events in the form of an Enumeration object. A display application creates an instance of the EpiCfgScanner object and adds the observed value of the Enumeration object to the Scan-List attribute. The scanner instance afterwards sends a notification when the Enumeration object reports a heart beat.

5.7.5 PeriCfgScanner (periodic configurable scanner) class

An instance of the PeriCfgScanner class is responsible for observing attributes of managed medical objects and for periodically reporting attribute values in the form of buffered event reports. A buffered event report contains the attribute values of all available attributes that are specified in the scan list, independent of attribute value changes.

If the scanner operates in a special superpositive mode, the buffered event report contains all value changes of attributes that occurred in the reporting period; otherwise, the report contains only the most recent attribute values.

Example: A data logger creates an instance of the PeriCfgScanner class and configures the scanner so that it sends an update of the observed value attributes of all Numeric objects in the MDIB every 15 s.

5.7.6 FastPeriCfgScanner (fast periodic configurable scanner) class

The FastPeriCfgScanner class is specialized for scanning the observed value attribute of RealTimeSampleArray objects. This special scanner class is further optimized for low-latency reporting and efficient communication bandwidth utilization, which is required to access real-time waveform data.

Example: A real-time display application (e.g., manager system) wants to display ECG waveforms. It instantiates a FastPeriCfgScanner object on the agent system (e.g., server device) and requests periodic updates of all ECG leads.

5.7.7 UcfgScanner (unconfigurable scanner) class

The UcfgScanner class is an abstract base class. An UcfgScanner object scans a predefined set of managed medical objects that cannot be modified. In other words, an UcfgScanner object typically is a reporting object that is specialized for one specific purpose.

The UcfgScanner class is abstract and cannot be instantiated.

5.7.8 ContextScanner class

An instance of the ContextScanner class is responsible for observing device configuration changes. After instantiation, a ContextScanner object is responsible for announcing the object instances in the device's MDIB. A ContextScanner object provides the object instance containment hierarchy and static attribute values.

In case of dynamic configuration changes, a ContextScanner object sends notifications about new object instances or deleted object instances.

Example: A data logger creates a ContextScanner instance in an agent MDIB to receive notifications about MDS configuration changes when new measurement modules are plugged in (i.e., new VMD instance) or when such a module is unplugged (i.e., VMD instance deleted).

5.7.9 AlertScanner class

An instance of the AlertScanner class is responsible for observing the alert-related attribute groups of objects modeled in the Alert Package. As alarming in general is security-sensitive, AlertScanner objects are not configurable (i.e., all or no Alert objects are scanned).

An AlertScanner object sends event reports periodically so that timeout conditions can be checked.

5.7.10 OperatingScanner class

An instance of the OperatingScanner class is responsible for providing all information about the operating and control system of a medical device.

In other words, an OperatingScanner instance maintains the configuration of Operation objects contained in SCOs (by sending CREATE notifications for Operation objects), it scans transaction-handling-related SCO attributes, and it scans Operation attributes. Because SCOs and Operation objects may have dependencies, the OperatingScanner is not configurable.