DIN EN ISO/IEEE 11073-10419

DIN

ICS 35.240.80

Entwurf

Einsprüche bis 2023-05-24
Vorgesehen als Ersatz für
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11073-10419:2016-10

Medizinische Informatik – Kommunikation von Geräten für die persönliche Gesundheit – Teil 10419: Gerätespezifikation – Insulinpumpe (ISO/IEEE 11073-10419:2019); Englische Fassung prEN ISO/IEEE 11073-10419:2023

Health informatics –
Personal health device communication –
Part 10419: Device specialization – Insulin pump (ISO/IEEE 11073-10419:2019);
English version prEN ISO/IEEE 11073-10419:2023

Informatique de santé –
Communication entre dispositifs de santé personnels –
Partie 10419: Spécialisation du dispositif – Pompe à insuline
(ISO/IEEE 11073-10419:2019);
Version anglaise prEN ISO/IEEE 11073-10419:2023

Anwendungswarnvermerk

Dieser Norm-Entwurf mit Erscheinungsdatum 2023-03-24 wird der Öffentlichkeit zur Prüfung und Stellungnahme vorgelegt.

Weil die beabsichtigte Norm von der vorliegenden Fassung abweichen kann, ist die Anwendung dieses Entwurfs besonders zu vereinbaren.

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Gesamtumfang 140 Seiten

DIN-Normenausschuss Medizin (NAMed)

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Nationales Vorwort

Dieses Dokument (prEN ISO/IEEE 11073-10419:2023) 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.

Für Deutschland hat hieran der Arbeitsausschuss NA 063-07-02 AA „Interoperabilität“ des Fachbereichs 7 „Medizinische Informatik“ im DIN-Normenausschusses Medizin (NAMed) mitgearbeitet.

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Der Bedarf für eine Deutsche Fassung wird derzeit beraten.

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

ISO/IEEE 11073-20601:2016 siehe DIN EN ISO/IEEE 11073-20601:2016-12

Aktuelle Informationen zu diesem Dokument können über die Internetseiten von DIN (www.din.de) durch eine Suche nach der Dokumentennummer aufgerufen werden.

Änderungen

Gegenüber DIN EN ISO 11073-10419:2016-10 wurden folgende Änderungen vorgenommen:

a) das Objekt PHD DM Status wurde hinzugefügt (in Bild 4 Modifizierung der DIM-Abbildung; 6.3.10 hinzugefügt, um diese neue Klasse zu beschreiben, A.3.11 hinzugefügt, um die ASN.1-Struktur zu beschreiben sowie Festlegung des Nomenklaturcodes für MDC PHD DM STAT in Anhang I);

b) die Aufzählungsklasse wurde um vier Attribute erweitert: Capability-Mask-Simple, Capability-Mask-Basic, State-Flag-Simple, und State-Flag-Basic (Einfügung neuer Attribute in 6.3.6.3; Einfügen der ASN.1-Struktur der neuen Attribute in A.3.5 sowie Einfügung der Nomenklatur-Codes in Anhang I);

c) Aktualisierungen zur Abdeckung der Spezialisierungen „hydra“ und „generic“ hinzugefügt;

d) Hinzufügung von Schedule-stored metric data transfer als 8.9.3.5;

e) Hinzufügung der Festlegung der Klasse „Schedule-store“ als 6.3.11 in Anhang G;

f) Hinzufügung der Festlegung von Schedule-segment class als 6.3.12 in Anhang G;

g) Hinzufügung der Nomenklatur für „Schedule-store“ und „Schedule-segment“ in Anhang I;

h) Hinzufügung des Konzepts „Schedule-store“ als Anhang K;

i) Hinzufügung der Schedule-store- und Schedule-segment-bezogenen Datentypen als A.11.9;

j) Aufnahme der Unterstützung für UDI(s) als neues MDS-Attribut;

k) Korrektur der redaktionellen Fehler in Agentensignal 8.22 und Managersignal 3.9 in Anhang E;

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l) Hinzufügung einer Anmerkung nach Tabelle E.4, um eine bessere Implementierung des Abbruchprozesses zu fördern;

m) DIM mit dem Scanner wurde korrigiert;

n) Angleichung der Festlegungen von msmt-value-exceed-boundaries (14) und msmt-state-ann-inhibited (15) an IEEE Std 11073-10404;

o) Festlegung von TSCHSXR FAIL SEGM TRY LATER für TrigSchedSegmXferRsp;

p) Hinzufügung von Context-Key zur Metric-Klasse für die aktuell relevanten Geräteinhalte und Einstellungen;

q) Hinzufügung Event-Context-Id zur Metric-Klasse, um einen Event-Kontext zu identifizieren;

r) in der Klasse Numeric wurden fünf Attribute hinzugefügt, die ursprünglich in anderen IEEE 11073-104zz Spezifikationen erweitert wurden: Alert-Op-State, Current-Limits, Alert-Op-Text-String, Measurement-Confidence-95, Threshold-Notification-Text-String;

s) dem Attribut Enum-Observed-Value-Simple-Bit-Str wurde ein Bitwert wie folgt zugewiesen: state (1), event (0);

t) Verschiebung des Unit-Codes von der Klasse Metric in die Klassen Numeric und RT-SA;

u) Literaturhinweise und Normative Verweisungen wurden aktualisiert;

v) der MDS-Scan-Event-Report wurde zu PM-store events und Schedule-store events hinzugefügt.

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Nationaler Anhang NA
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Begriffe

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

Für die Anwendung dieses Dokuments gelten die folgenden Begriffe.

ISO und IEC stellen terminologische Datenbanken für die Verwendung in der Normung unter den folgenden Adressen bereit:

— ISO Online Browsing Platform: verfügbar unter https://www.iso.org/obp

— IEC Electropedia: verfügbar unter http://www.electropedia.org/

3.1
Agent
en **agent**
Knoten, der persönliche Gesundheitsdaten sammelt und an einen angeschlossenen Manager weiterleitet

3.2
künstliche Bauchspeicheldrüse
en **artificial pancreas**
System, das durch Kombination von Diabetesgeräten eine ähnliche Funktionalität wie eine Bauchspeicheldrüse bereitstellt. Beispiele hierfür sind die Verknüpfung eines kontinuierlichen Glukose-Monitors mit einer Insulinpumpe, die eine automatische Reduzierung oder Erhöhung der Insulininfusion ermöglichen, basierend auf festgelegten Grenzwerten für die gemessene interstitielle Glukose

3.3
Basalinsulin
en **basal insulin**
Insulin, das benötigt wird, um den Insulingrundbedarf des Körpers zu decken

3.3
Basalrate
en **basal rate**
Rate des kontinuierlich zugeführten Insulins, um den Insulingrundbedarf des Körpers zu decken

3.4
Basalratenprofil
en **basal rate profile**
Profil, das den zeitabhängigen Verlauf der Basalrate über einem periodischen Zeitintervall festlegt (beispielsweise 24 Stunden, beginnend um Mitternacht)

3.5
Blutglucose
en **blood glucose**
Glukose-Konzentration im Blut

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3.6
Bolus
en **bolus**
Einzeldosis eines Medikaments, welche typischerweise durch Infusion verabreicht wird. Siehe auch: Bolusinsulin

3.7
Bolusinsulin
en **bolus insulin**
Insulin, welches benötigt wird, um die Nahrungsaufnahme auszugleichen oder um zu hohe Blutzuckerwerte zu korrigieren

3.8
Klasse
en **class**
im objektorientierten Modell beschreibt eine Klasse die Attribute, Methoden und Ereignisse, die Objekte benutzen, welche aus dieser Klasse instantiiert werden

3.9
Manager
Verarbeitungsmaschine
en **manager**
compute engine
Knoten, der Daten von einem oder mehreren angeschlossenen Agentensystem erhält. Manager können z. B. auch mobile Telefone, gesundheitsbezogene Geräte, Digitalempfänger oder Computersysteme sein

3.10
Korrekturbolus
en **correction bolus**
Bolus, um hohe Blutzuckerwerte zu korrigieren. Siehe auch: Bolus.

3.11
Tages-Basaldosis
en **daily basal dose**
Gesamtmenge des Basalinsulins, das in 24 Stunden bereitgestellt wird, beginnend um Mitternacht

3.12
Gerät
en **device**
physische Apparatur, die entweder eine Agenten- oder eine Managerrolle wahrnimmt

3.13
Langzeit-Bolus
en **extended bolus**
Bolus, der über einen längeren Zeitraum für eine bestimmte Zeitdauer verabreicht wird. Siehe auch: Bolus.

3.14
schnellwirkender Bolus
en **fast bolus**
Bolus, der über einen sehr kurzen Zeitraum verabreicht wird und der mit unendlich kleiner Dauer berücksichtigt und durch die Infusionsmenge angegeben werden kann. Siehe auch: Bolus.

3.15
Glukagon
en **glucagon**
natürlich vorkommendes Hormon, das von der Bauchspeicheldrüse freigesetzt wird, wenn der Blutzuckerspiegel niedrig ist

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3.16
Glukose
en **glucose**
Hauptenergiequelle, die von den Körperzellen genutzt wird; wird im Allgemeinen als Zucker bezeichnet

3.17
Dateinummer
Objekt-Handle
en **handle**
obj-handle
vorzeichenlose 16-bit-Zahl, die lokal einmalig vergeben wird und der Identifizierung der Objektinstanz in einem Agenten dient

3.18
Infusionsset
en **infusion set**
Schlauchsystem mit Kanüle, das verwendet wird, um den Insulinbehälter mit dem Körper zu verbinden

3.19
Insulin
en **insulin**
natürlich vorkommendes Hormon, das für den Kohlenhydratstoffwechsel benötigt wird. Insulin reguliert den Weg um Zucker, Fett und Proteine für die Zellen bereitzustellen und die Art, wie sie gespeichert oder in Energie umgewandelt werden.

3.20
Insulin-zu-Kohlenhydrat-Verhältnis
en **insulin-to-carbohydrate ratio (I:CHO)**
Menge an Kohlenhydraten, die durch eine einzige Insulineinheit gedeckt oder beseitigt wird

3.21
Insulinempfindlichkeitsfaktor
Korrekturfaktor
en **insulin sensitivity factor (ISF)**
correction factor
geschätzte Menge von Blutzucker, die durch eine einzige Insulineinheit reduziert wird

3.22
internationale Einheit
en **international unit (IU)**
Maßeinheit in der Pharmazie, die für die Messung der Menge einer Substanz eingesetzt wird

3.23
Mahlzeitenbolus
en **meal bolus**
Bolus, der dazu dient, die Nahrungsaufnahme zu kompensieren. Siehe auch: Bolus.

3.24
Kombinationsbolus
en **multi-wave bolus**
Kombination aus einem schnellwirkenden Bolus mit einem Langzeit-Bolus; ein Teil der Bolus-Menge wird sofort zugeführt, während der andere über einen bestimmten Zeitraum abgegeben wird

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3.25
Objekt
en **object**
in der objektorientierten Modellierung, eine besondere Instantiierung einer Klasse. Die Instantiierung legt Attribute, Methoden und Ereignisse der Klasse fest

3.26
Okklusion
en **occlusion**
kompletter Verschluss des Infusionssets, der die Verabreichung von Insulin verhindert

3.27
persönliches gesundheitsbezogenes Gerät
persönliches telemedizinisches Gerät
en **personal health device**
personal telehealth device
Gerät, das für persönliche gesundheitsbezogene Anwendungen verwendet wird

3.28
Kolbenstange
en **piston rod**
mechanische Vorrichtung, um den Kolben des Insulinbehälters zu bewegen

3.29
Grundeinstellung
en **priming**
Füllung des Flüssigkeitsbereiches mit Insulin (z. B. nach dem Austausch des Behälters und/oder Infusionssets)

3.30
Behälter
en **reservoir**
Insulinzufuhr einer Insulinpumpe

3.31
temporäre Basalrate
en **temporary basal rate**
vorübergehende Einstellung der Basalrate

3.32
Tagesgesamtdosis
en **total daily dose**
Gesamtmenge des Insulins, die während eines Tages (d. h. in 24 Stunden, beginnend um Mitternacht) bereitgestellt wird. Diese Menge beinhaltet sowohl Basalinsulin als auch Bolusinsulin.

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Nationaler Anhang NB
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Nationale Hinweise

Die ISO/IEEE 11073-Standardfamilie ermöglicht die Datenübertragung zwischen Medizingeräten und Computersystemen. Sie erlaubt die automatisierte, detaillierte Erfassung von personenbezogenen Vitaldaten und Funktionsparametern durch die Verwendung von Überwachungs- und Therapiegeräten – beispielsweise auf einer Intensivstation oder im Operationssaal, aber auch im häuslichen oder privaten Umfeld. Die primären Ziele dabei sind:

— Bereitstellung von „Plug-and-Play"-Funktionalität und Interoperabilität mit Patienten verbundener bzw. personenbezogener Medizingeräte für Realzeitanwendungen.

— Vereinfachung des effizienten Austausches gemessener Vitaldaten, relevanter Kontextinformation sowie Betriebsdaten der verwendeten Medizingeräte.

„Realzeit" bedeutet hier, dass Daten von ggf. mehreren, verschiedenartigen Medizingeräten zeitgenau erfasst und in Bruchteilen von Sekunden dargestellt oder verarbeitet werden können. „Plug-and-Play" bedeutet, dass Anwender lediglich die Kommunikationsverbindung zu einem Gerät herstellen müssen. Automatisch, d. h. ohne menschlichen Eingriff, erfolgen dessen Erkennung durch das System, die Konfiguration von Kommunikationsparametern sowie gegebenenfalls der Applikation und schließlich die Aufnahme der Datenübertragung.

Dieses Dokument legt innerhalb der ISO/IEEE 11073-Standardfamilie für die Kommunikation gesundheitsbezogener telemedizinischer Geräte eine verbindliche Definition für die Kommunikation zwischen Insulinpumpen und Datenverarbeitungsgeräten (wie mobilen Telefonen, Arbeitsplatzrechnern, gesundheitsbezogenen persönlichen Geräten, Settop-Boxen) derart fest, dass „Plug-and-Play"-Interoperabilität ermöglicht wird. Sie benutzt Teile existierende Normen, insbesondere ISO/IEEE 11073 Normen zu Terminologie, Informationsmodellen, Anwendungsprofilen und Datentransport. Dieses Dokument legt die Verwendung bestimmter Codes, Formate und Verhaltensweisen in telemedizinischen Umgebungen fest und schränkt die Optionalität in den zugrunde liegenden Rahmenbedingungen ein, um Interoperabilität zu erleichtern. Dieses Dokument legt gemeinsame Kernfunktionen für die Kommunikation von Insulinpumpen fest.

In diesem Zusammenhang werden Insulinpumpen als Geräte definiert, die für die Behandlung von Diabetes mellitus bestimmt sind, auch bekannt als kontinuierliche subkutane Insulininfusion (CSII)-Therapie.

Dieses Dokument unterstützt die Datenmodellierung nach der Norm ISO/IEEE 11073-20601, und legt nicht das Messverfahren fest.

Dieses Dokument entspricht der Notwendigkeit eines offen definierten, unabhängigen Standards für den geregelten Austausch von Informationen zwischen persönlichen gesundheitsbezogenen Geräten und Datenverarbeitungsgeräten (wie mobilen Telefonen, Arbeitsplatzrechnern, gesundheitsbezogenen persönlichen Geräten, Settop-Boxen). Interoperabilität ist der Schlüssel zum Wachstum des potentiellen Markts für diese Geräte und ermöglicht, dass sich Menschen besser informieren und stärker an ihrer gesundheitlichen Betreuung beteiligen.

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Nationaler Anhang NC
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Literaturhinweise

DIN EN ISO/IEEE 11073-20601:2016-12, *Medizinische Informatik — Kommunikation von Geräten für die persönliche Gesundheit — Teil 20601: Anwendungsprofil — Optimiertes Datenübertragungsprotokoll (ISO/IEEE 11073-20601:2016, einschließlich Cor.1:2016); Englische Fassung EN ISO 11073-20601:2016*

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ISO/IEEE 11073-10419 was prepared by the IEEE 11073 Standards Committee of the IEEE Engineering in Medicine and Biology Society (as IEEE Std 11073-10419-2017) and drafted in accordance with its editorial rules. It was adopted, under the “fast-track procedure” defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE, by Technical Committee ISO/TC 215, *Health informatics*.

This second edition cancels and replaces the first edition (ISO 11073-10419:2016), which has been technically revised.

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Abstract: Within the context of the ISO/IEEE 11073 family of standards for device communication, a normative definition of communication between personal telehealth insulin pump devices and compute engines (e.g., cell phones, personal computers, personal health appliances, set top boxes), in a manner that enables plug-and-play interoperability, is established in this standard. It leverages appropriate portions of existing standards including ISO/IEEE 11073 terminology, information models, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments restricting optionality in base frameworks in favor of interoperability. The standard defines a common core of communication functionality for personal telehealth insulin pump devices.

Keywords: IEEE 11073-10419™, insulin pump, medical device communication, personal health devices

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Introduction

This introduction is not part of IEEE Std 11073-10419-2017, Health informatics—Personal health device communication—Part 10419: Device Specialization—Insulin Pump.

ISO/IEEE 11073 standards enable communication between medical devices and external computer systems. This document uses the optimized framework created in ISO/IEEE 11073-20601:2016 and describes a specific, interoperable communication approach for insulin pumps.[1] These standards align with, and draw on, the existing clinically focused standards to provide support for communication of data from clinical or personal health devices (PHDs).

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

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Health informatics—Personal health device communication

Part 10419: Device Specialization—Insulin Pump

1. Overview

1.1 Scope

This standard establishes a normative definition of communication between personal telehealth insulin pump devices (agents) and managers (e.g., cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play interoperability. It leverages work done in other ISO/IEEE 11073 standards including existing terminology, information profiles, application profile standards, and transport standards. It specifies the use of specific term codes, formats, and behaviors in telehealth environments, restricting optionality in base frameworks in favor of interoperability. This standard defines a common core functionality of personal telehealth insulin pump devices.

In the context of personal health devices (PHDs), an insulin pump is a medical device used for the administration of insulin in the treatment of diabetes mellitus, also known as continuous subcutaneous insulin infusion (CSII) therapy.

This standard provides the data modeling according to ISO/IEEE 11073-20601 and does not specify the measurement method.

1.2 Purpose

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

1.3 Context

See ISO/IEEE 11073-20601:2016 for an overview of the environment within which this standard is written.[2]

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

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This standard defines the device specialization for the insulin pump, being a specific agent type, and provides a description of the device concepts, its capabilities, and its implementation according to this standard.

This standard is based on ISO/IEEE 11073-20601:2016, which in turn draw information from both ISO/IEEE 11073-10201:2004 [B8] and ISO/IEEE 11073-20101:2004 [B9].[3] The medical device encoding rules (MDER) used within this standard are fully described in ISO/IEEE 11073-20601:2016.

This standard reproduces relevant portions of the nomenclature found in ISO/IEEE 11073-10101:2004 [B6] and ISO/IEEE 11073-10101a:2015 [B7] and adds new nomenclature codes for the purposes of this standard. Among these standards and ISO/IEEE 11073-20601:2016, all required nomenclature codes for implementation are documented.

NOTE—In this standard, ISO/IEEE 11073-104zz is used to refer to the collection of device specialization standards that utilize ISO/IEEE 11073-20601, where zz can be any number from 01 to 99, inclusive.[4]

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used; therefore, 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/IEEE 11073-20601:2016, Health informatics—Personal health device communication—Part 20601: Application Profile—Optimized Exchange Protocol.[5]

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

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 consulted for terms not defined in this clause.[6]

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

artificial pancreas: A system combining diabetes devices to provide similar functionality as a pancreas. Examples include linking a continuous glucose monitor to an insulin pump to automatically reduce or increase insulin infusion based upon specified thresholds of measured interstitial glucose.

basal insulin: Insulin required to cover the basic insulin needs of the body.

basal rate: Rate of continuously delivered insulin to cover the basic insulin needs of the body.

[3] The numbers in brackets correspond to the numbers of the bibliography in Annex A.
[4] Notes in text, tables, and figures of a standard are given for information only and do not contain requirements needed to implement the standard.
[5] ISO/IEEE publications are available from the ISO Central Secretariat (http://www.iso.ch/). ISO/IEEE publications are also available in the United States from The Institute of Electrical and Electronics Engineers (http://standards.ieee.org/).
[6] *IEEE Standards Dictionary Online* is available at http://dictionary.ieee.org.

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basal rate profile: Profile defining the time-dependent course of the basal rate over a periodic time interval (e.g., 24 hours, beginning at midnight).

blood glucose: Glucose concentration in the blood.

bolus: A single dose of a medication typically administered by infusion. *See also:* **bolus insulin**.

bolus insulin: Insulin required to cover the intake of food or to correct high blood glucose levels.

class: In object-oriented modeling, a term collectively describing the attributes, methods, and events utilized by objects instantiated from the class.

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

correction bolus: A bolus to correct high blood glucose levels. *See also:* **bolus**.

daily basal dose: Total amount of basal insulin delivered in 24 hours, beginning at midnight.

device: A physical apparatus implementing either an agent or a manager role.

extended bolus: A bolus given over an extended period of time with a specified duration. *See also:* **bolus**.

fast bolus: A bolus given over a very short period that can be considered as having infinitesimal duration and specified by amount of infusion. *See also:* **bolus**.

glucagon: Naturally occurring hormone released by the pancreas when glucose levels are low.

glucose: The major source of energy used by the body cells. Glucose is commonly referred to as *sugar*.

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

infusion set: A tubing system with cannula that interfaces the insulin reservoir to the body.

insulin: Naturally occurring hormone required for carbohydrate metabolism. Insulin regulates the way sugar, fat, and proteins are moved into the cells and the way they are stored or used for energy.

insulin-to-carbohydrate ratio (I:CHO): Amount of carbohydrate covered or disposed of by a single unit of insulin.

insulin sensitivity factor (ISF): An estimated amount of blood glucose reduced by a single unit of insulin. *Syn:* **correction factor**.

international unit (IU): Unit of measurement used in pharmacology for the measurement of the amount of a substance.

manager: A node receiving data from one or more agent systems. Some examples of managers include a cellular phone, health appliance, set top box, or computer system.

meal bolus: A bolus to compensate for meal intake. *See also:* **bolus**.

multi-wave bolus: A bolus combining a fast bolus with an extended bolus. One part of the bolus amount is delivered immediately while the other is delivered over a specific period of time.

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

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

occlusion: Total obstruction of the infusion set that prevents administering insulin.

personal health device (PHD): A device used in personal health applications.

personal telehealth device: *See:* **personal health device (PHD)**.

piston rod: Mechanical apparatus to propel the plunger of the insulin reservoir.

priming: The filling of the fluidic path with insulin (e.g., after replacement of the reservoir and/or infusion set).

reservoir: The insulin supply of an insulin pump.

temporary basal rate: Temporary adjustment of the basal rate.

total daily dose: The total amount of insulin delivered during one day (i.e., 24 hours, beginning at midnight). This amount contains basal insulin as well as bolus insulin.

3.2 Acronyms and abbreviations

AP	artificial pancreas
APDU	application protocol data unit
ASN.1	Abstract Syntax Notation One
CSII	continuous subcutaneous insulin infusion, commonly known as *insulin pump therapy*
DIM	domain information model
DM	disease management
EUI-64	extended unique identifier (64 bits)
HCP	health care professional
I:CHO	insulin-to-carbohydrate ratio
ICS	implementation conformance statement
ID	identifier
ISF	insulin sensitivity factor
IU	international unit
MDC	medical device communication
MDER	medical device encoding rules
MDS	medical device system
MOC	managed object class
OID	object identifier
PDU	protocol data unit
PHD	personal health device
VMO	virtual medical object
VMS	virtual medical system

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4. Introduction to ISO/IEEE 11073 personal health devices (PHDs)

4.1 General

This standard and the remainder of the series of ISO/IEEE 11073 PHD standards fit in the larger context of the ISO/IEEE 11073 series of standards. The full suite of standards enables agents to interconnect and interoperate with managers and with computerized health-care information systems. See ISO/IEEE 11073-20601:2016 for a description of the guiding principles for this series of ISO/IEEE 11073 PHD standards.

ISO/IEEE 11073-20601:2016 supports the modeling and implementation of an extensive set of PHDs. This standard defines aspects of the insulin pump device. It describes all aspects necessary to implement the application layer services and data exchange protocol between an ISO/IEEE 11073 PHD insulin pump agent and a manager. This standard defines a subset of the objects and functionality contained in ISO/IEEE 11073-20601:2016 and extends and adds definitions where appropriate. All new definitions are given in Annex B in Abstract Syntax Notation One (ASN.1) (ITU-T X.680-2002 [B10]). Nomenclature codes referenced in this standard that are not defined in ISO/IEEE 11073-20601:2016 are normatively defined in Annex C.

4.2 Introduction to ISO/IEEE 11073-20601 modeling constructs

4.2.1 General

The ISO/IEEE 11073 series of standards, and in particular ISO/IEEE 11073-20601:2016, is based on an object-oriented systems management paradigm. The overall system model is divided into three principal components: the domain information model (DIM), the service model, and the communication model. See ISO/IEEE 11073-20601:2016 for a detailed description of the modeling constructs.

4.2.2 Domain information model (DIM)

The DIM is a hierarchical model that describes an agent as a set of objects. These objects and their attributes represent the elements that control behavior and report on the status of the agent and data that an agent can communicate to a manager. Communication between the agent and the manager is defined by the application protocol in the ISO/IEEE 11073-20601:2016.

4.2.3 Service model

The service model defines the conceptual mechanisms for the data exchange services. Such services are mapped to messages that are exchanged between the agent and the manager. Protocol messages within the ISO/IEEE 11073 series of standards are defined in ASN.1. The messages defined in ISO/IEEE 11073-20601:2016 can coexist with messages defined in other standard application profiles defined in the ISO/IEEE 11073 series of standards.

4.2.4 Communication model

In general, the communication model supports the topology of one or more agents communicating over logical point-to-point connections to a single manager. For each logical point-to-point connection, the dynamic system behavior is defined by a connection state machine as specified in ISO/IEEE 11073-20601:2016.

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4.2.5 Implementing the models

An agent implementing this standard shall implement all mandatory elements of the information, service, and communication models as well as all conditional elements where the condition is met. The agent should implement the recommended elements, and it may implement any combination of the optional elements. A manager implementing this standard shall utilize at least one of the mandatory, conditional, recommended, or optional elements. In this context, *utilize* means to use the element as part of the primary function of the manager device. For example, a manager whose primary function is to display data would need to display a piece of data in the element in order to utilize it.

4.3 Compliance with other standards

Devices that comply with this standard may also be required to comply with other domain-and device-specific standards that supersede the requirements of this standard with respect to issues including safety, reliability, and risk management. A user of this standard is expected to be familiar with all other such standards that apply and to comply with any higher specifications thus imposed. Typically, medical devices should comply with the IEC 60601-1:2005 [B1] base standards with respect to electrical and mechanical safety and any device-specific standard as might be defined in the IEC 60601-2 [B2] series of standards. Software aspects may apply through standards such as IEC 62304:2006/EN 62304:2006 [B3].

Devices that comply with this standard implement higher layers of network software and utilize lower layers as appropriate to the application. The requirements on performance of such applications and conformance are defined elsewhere and are outside the scope of this standard. Moreover, the use of any medical equipment is subject to risk assessment and risk management appropriate to the application. Some relevant examples are ISO 14971:2007 [B5] and IEC 80001-1:2010 [B4]. The requirements of such risk assessment and risk management and conformance are outside the scope of this standard.

5. Insulin pump device concepts and modalities

5.1 General

This clause presents the general concepts of insulin pump devices. In the context of PHDs in this family of standards, an insulin pump is a device that administers insulin at a defined amount to the human body. Insulin pump devices are primarily used in the continuous subcutaneous insulin infusion (CSII) therapy of type 1 diabetes mellitus. This type of diabetes mellitus is characterized by loss of the insulin-producing beta cells of the islets of Langerhans in the pancreas. Insulin pumps typically inject insulin into the subcutaneous layer of fat tissue under the skin through an infusion set. Preferred sites for the cannula are the abdomen, lumbar region, thighs, buttocks, and the upper arms.

Insulin is a hormone that affects the metabolism and other body functions. It regulates, together with glucagon, the glucose level in the blood. Failure to produce sufficient insulin to maintain the blood glucose in the normal range leads to conditions of temporarily or persistently high blood sugar (hyperglycemia).

The objective of CSII therapy, also known as insulin pump therapy, is to mimic the insulin secretion of the healthy body. Insulin pump therapy therefore differentiates between basal insulin and bolus insulin. Basal insulin, sometimes also referred to as *background* insulin, regulates the blood glucose level without taking into account any food intake. In the context of the CSII therapy, basal insulin is continuously administered at a given rate depending on the fluctuating need throughout the day. By contrast, bolus insulin compensates for an increased need for insulin induced by food intake. This is also known as *meal* bolus, and the insulin dosage can be determined with the knowledge of the user's insulin-to-carbohydrate ratio (I:CHO) (the amount of carbohydrate covered by a unit of insulin). In addition, bolus insulin may also be administered to decrease a temporarily high blood glucose level. This is often referred to as *correction* bolus. Meal or correction boluses can be delivered as a standard fast bolus, extended bolus, or as a multi-

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wave bolus. Fast bolus is an infusion of insulin over a very short period similar to a pen injection that can be considered as having infinitesimal duration. An extended bolus is an infusion of insulin over a longer period extending the insulin delivery. A multi-wave bolus combines a fast bolus with an extended bolus; one part of the bolus amount is delivered immediately while the other is delivered over a specific period of time. This type of bolus is suitable for meals that contain both fast and slowly digestible carbohydrates or long meals with several courses.

Although the distinction between basal and bolus insulin has a high relevance for the CSII therapy, the insulin pump typically delivers a single insulin type for both delivery methods. Unlike the intensified conventional therapy (ICT, injection therapy, pen therapy) where typically a combination of injections with fast-acting and slow-acting insulin is utilized, the insulin pump therapy generally uses rapid- or fast-acting insulin. Another term for these types of insulin is *insulin analog*.

Many insulin pump devices allow the pump user to program basal rate profiles that define the fluctuating delivery of basal insulin of the pump in the course of the day. These profile settings are often referred to as circadian profiles. Well-adjusted basal rate profiles generally cover the insulin pump user's need for basal insulin and there is normally no necessity to adjust these profiles on a daily basis. However, there are situations in which the need for basal insulin deviates at such a rate that a temporary adjustment of the basal delivery is indicated. Phases of stress, intensified physical activity, illness, and menses are counted among the reasons for increased or reduced need for basal insulin. The temporary basal rate is a means to make short-term adjustments to the basal insulin delivery. Two different concepts for the temporary basal rate are currently well accepted in the area of insulin pump therapy. The first concept applies a scaling factor to the programmed basal rate for a certain period of time. The second concept consists in overriding the programmed basal rate with a specific value for a certain time period.

The unit of measurement to define the dose of insulin is international unit (IU). One IU of insulin is the biological equivalent of 1/22 mg of pure crystalline insulin. The concentration of insulin in an insulin solution is defined by international units per milliliter (i.e., IU/mL). In pharmacology, it is also very common to indicate the concentration of insulin solutions by the letter U followed by the number of international units per milliliter. For example, a concentration of 100 IU/mL is denominated as U100.

5.2 Device types

Insulin pump devices are generally designed to be portable and permanently connected to the body.

The structural shape of insulin pumps may vary, but insulin pump devices typically include the following components: the pump unit, a disposable insulin reservoir, and a disposable infusion set.

The pump unit typically comprises a computing unit and a dosing mechanism, both powered by a battery. Additionally, pump units may contain several user interface elements such as displays, buttons, or apparatuses to generate visual, haptic, or acoustic signals.

The disposable insulin reservoir typically consists of a glass or plastic ampulla with a volumetric capacity of a few milliliters of insulin solution. Depending on the insulin need of the pump user, this capacity is sufficient for provisioning insulin for several days.

The disposable infusion set interfaces the insulin reservoir to the human body. It generally comprises an adapter that connects to the insulin reservoir, a tubing system and a cannula that is inserted into the subcutaneous fat tissue. It is generally recommended to replace the infusion set after 2 to 3 days of usage for sterility reasons and to help prevent irritation at the insertion site.

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5.3 Collected data

5.3.1 General

The insulin pump is a portable device and therefore may not be connected to a manager while collecting data. The two main use cases for an insulin pump agent to connect to a manager and send its data are the following:

— The insulin pump user visits a health care professional (HCP) to examine the adequacy of the therapy. The HCP normally compares the historic data from the insulin pump with the corresponding data from a blood glucose meter or continuous glucose monitor device to derive necessary adjustments to the insulin pump therapy. As the interval between such visits may constitute several months, insulin pumps are typically capable of storing data for such time periods.

— The insulin pump user connects the insulin pump agent to a manager at home to examine the adequacy of the therapy and to apply adjustments when indicated. This tends to happen on a more frequent basis (e.g., once per week).

In addition to the two use cases above, an insulin pump agent may also be continuously connected to a manager to report collected data (e.g., artificial pancreas).

5.3.2 Current bolus setting

The current bolus setting represents the amount of insulin requested to be delivered as a bolus and is reported before the pump delivers the bolus. A bolus is typically initiated by the insulin pump user to compensate for an increased need for insulin induced by intake of food containing a relatively high quantity of carbohydrates (e.g., meal bolus). A bolus may also be indicated to decrease a temporarily high blood glucose level (e.g., correction bolus).

The quantity of insulin specified in a current bolus setting can be delivered in a theoretically infinitesimal period of time (e.g., fast bolus) or can be delivered over a defined period of time (e.g., extended bolus) or as a combination of a fast bolus with an extended bolus (e.g., multi-wave bolus). The duration of an extended bolus shall be reported as a measure active period.

A current bolus setting can be set to be delivered at a later time. In this instance, the current bolus setting shall be used with the pending bolus delay together to specify the amount of delay between programming a current bolus setting and the expected bolus delivered.

A current bolus setting can be cancelled. In this instance, the current bolus setting shall be used with the insulin pump status to specify the bolus canceled.

A bolus amount can be set manually by the user, or recommended by the insulin pump’s bolus calculator, or commanded from an artificial pancreas controller. If an insulin pump device has a bolus calculator, the user may accept or change the recommended amount of insulin.

The unit for the bolus setting is international units.

NOTE—This object represents a device setting and not a measurement value.

5.3.3 Pending bolus delay

The pending bolus delay specifies the delay between programming a current bolus setting and the expected bolus delivered. This setting is helpful for patients with delayed digestion (gastroparesis).

The unit for the pending bolus delay is in minutes.

NOTE—This object represents a device setting and not a measurement value.

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5.3.4 Bolus delivered

The bolus delivered measurement represents the amount of insulin effectively delivered by the insulin pump as a bolus and is reported after the pump has delivered the bolus.

The measurement represents the delivered amount of insulin for a bolus and the modality can be described as a fast bolus, extended bolus, or multi-wave bolus, and the reason for delivering the bolus as meal bolus or correction bolus (Figure 1). The unit for the bolus delivered is international units.

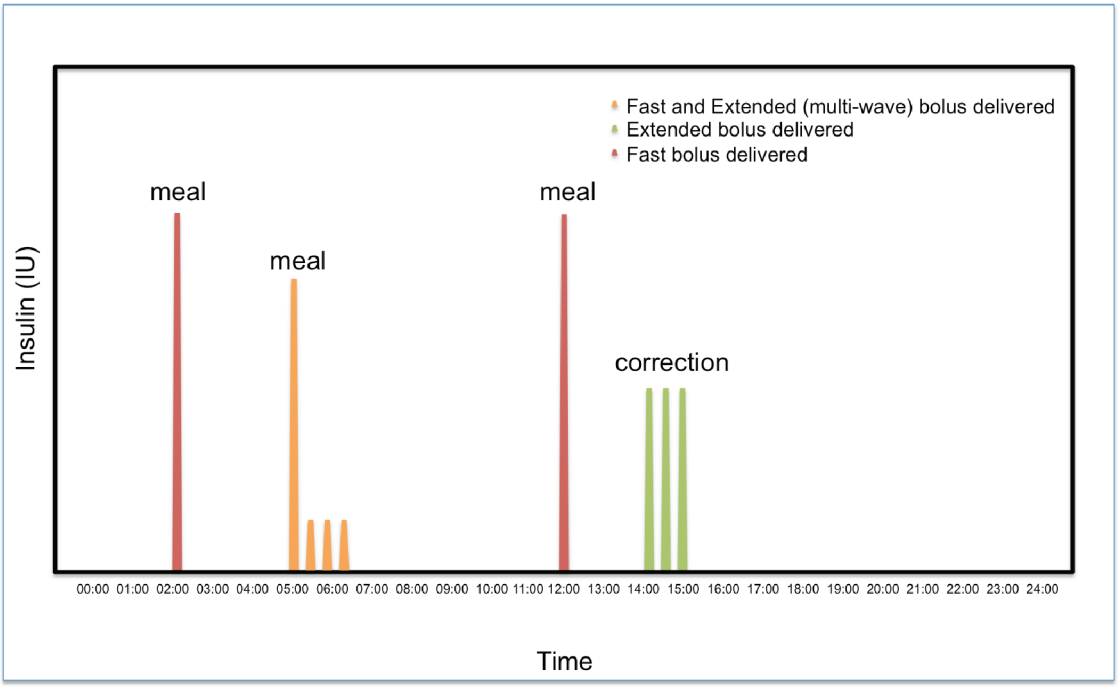


Figure 1—Example of bolus delivered

5.3.5 Basal rate schedule setting

The purpose of a basal rate schedule setting is to define the amount of basal insulin programmed in an insulin pump to be delivered for a specified schedule according to the individually fluctuating physiological needs. One or more basal rate schedule settings form a 24 hour basal profile.

The unit of a basal rate schedule setting is international units per hour.

NOTE—This object represents a device setting and not a measurement value.

5.3.6 Basal profile setting

Insulin pump devices typically offer the option of programming multiple basal profile settings in order to easily meet changing insulin needs (e.g., work day versus weekend).

In the context of CSII, a basal rate designates the amount of basal insulin programmed to deliver over a specified period of time.

The basal profile setting is a schedule-segment that consists of a series of basal rate schedule settings programmed on the insulin pump device. The basal profile setting has a schedule that typically begins at 12 a.m. and ends at 12 a.m. the following day accumulating a total duration of 24 hours (Figure 2).

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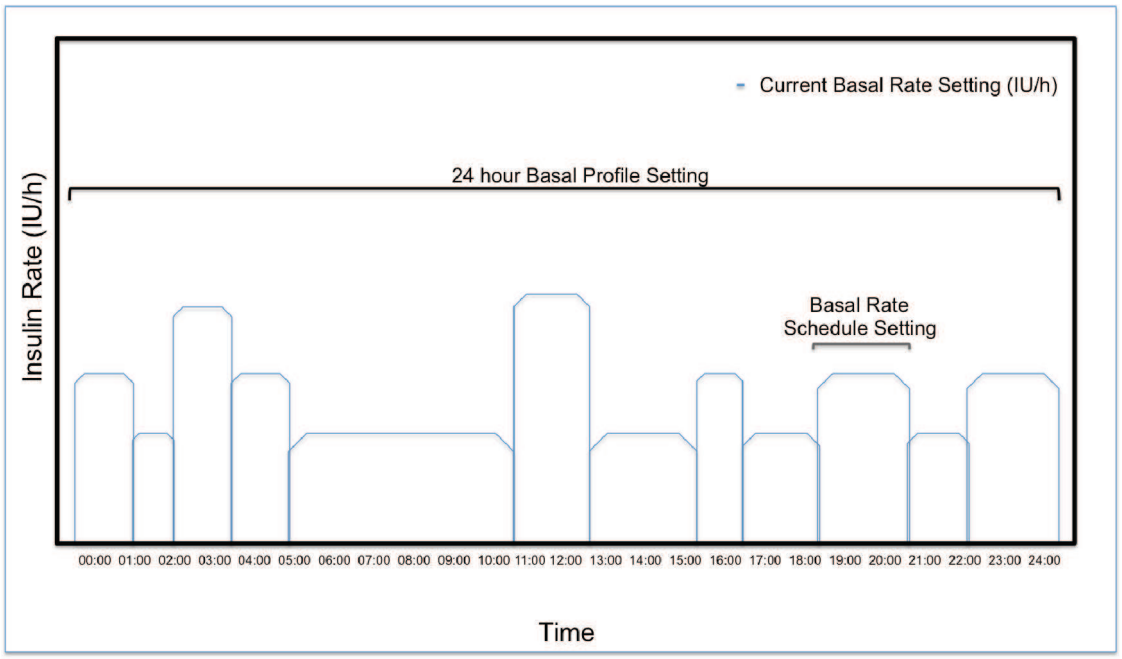


Figure 2—Example of basal profile setting consisting of basal rate schedule settings

Insulin pump devices typically offer the option of programming multiple basal profile settings in order to easily meet changing insulin needs (e.g., work day versus weekend). The basal profile setting will also have a unique identifier specified by the manufacturer to identify a basal profile setting.

If an insulin pump deviace supports programming basal profile settings, an active basal profile setting can be selected.

NOTE—This object represents a device setting and not a measurement value.

5.3.7 Current basal rate setting

The current basal rate setting represents the most recent basal rate to be delivered by the pump and is reported before the pump delivers the basal rate. Current basal rate setting may be initiated by a programmed basal profile or a temporary basal rate adjustment made by the user.

A basal profile is a scheduled sequence of basal rate schedule settings programmed on the insulin device. The active basal profile and current time may define the current basal rate setting.

Alternatively, a user may initiate a temporary basal rate adjustment as a result of a temporarily changed need. This adjustment remains active for a defined period of time and afterwards the current basal rate setting will revert to the programmed basal profile. The temporary basal rate setting can be initiated by a *relative* or an *absolute* adjustment.

A *relative* temporary basal rate setting applies a dimensionless scaling factor to the current basal rate for the active basal profile. Therefore if the relative temporary basal rate is active, the rate delivery equals the value of the reference factor multiplied by the basal rates given by the active basal profile for a given period of time. A relative temporary basal rate shall be the calculated rate after applying the scaling factor.

An *absolute* temporary basal rate setting overrides the basal rates given by the active basal rate profile for a given period of time. Therefore, if the absolute temporary basal rate is active, the rate delivery equals the value of the absolute temporary basal rate for a given period of time.

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This standard assumes that the effective delivery of basal insulin can be represented or approximated by discrete values of constant delivery rate over time. This standard assumes that the temporary basal rate setting overrides the basal rates given by the active basal rate profile. Therefore, if the temporary basal rate (either relative or absolute) is active, the rate of the actual basal insulin delivery equals the value of the temporary basal rate. The unit of the delivery rate is international units per hour.

NOTE—This object represents a device setting and not a measurement value.

5.3.8 Basal delivered

The basal delivered measurement represents the amount of insulin effectively delivered as a basal by an insulin pump and is reported after the pump has delivered the basal. An insulin pump device commonly utilizes semi-continuous infusion and incrementally injects discrete amounts (often called a *micro-bolus*) of insulin to satisfy the current basal rate setting (Figure 3). The insulin pump is responsible for determining the frequency of the basal amount to be reported (e.g., insulin pump may report the amount of insulin delivered at the end of a basal rate or intermittently as micro-boluses).

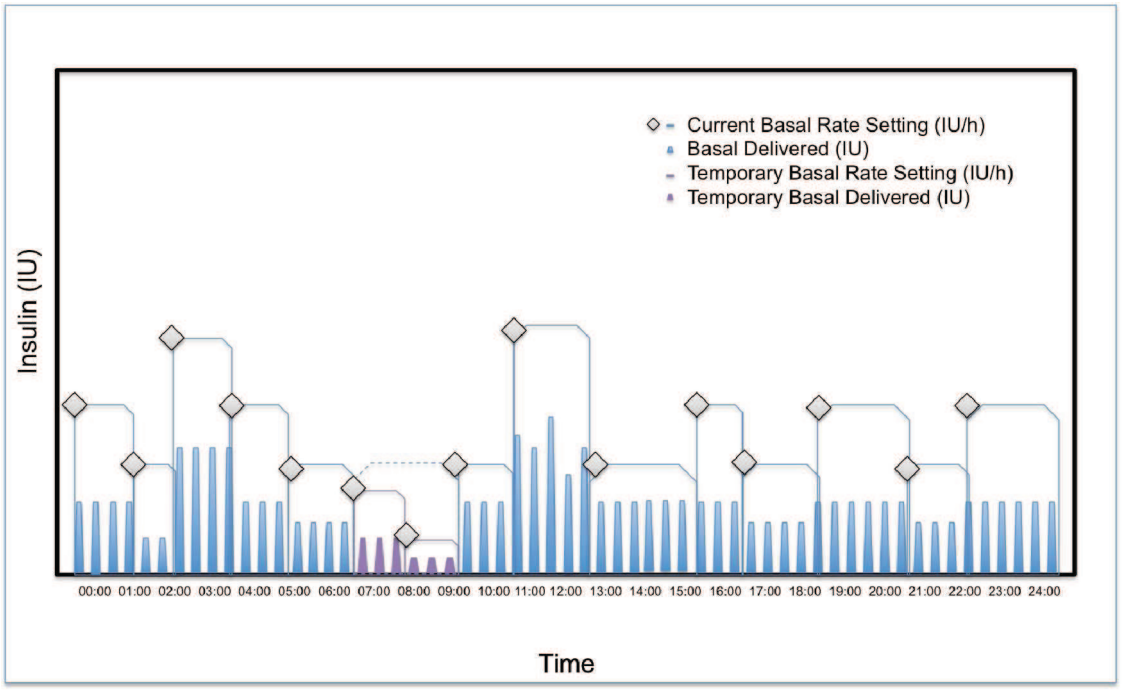


Figure 3—Example of basal rate setting and basal delivered

The measurement represents the delivered amount of basal insulin and can be described as a programmed basal rate, basal rate set by a controller, a temporary absolute basal, temporary relative basal, or undetermined basal rate. The unit for the basal delivered measurement is international units.

5.3.9 Insulin reservoir remaining

The insulin reservoir remaining measurement represents the amount of insulin remaining in the reservoir. The reservoir holds insulin inside the insulin pump and can have varying capacity. As the pump delivers insulin, the insulin amount in the reservoir decreases. When the reservoir is empty, users typically refill and insert a new reservoir into the insulin pump. The insulin pump is responsible for determining the frequency of the insulin reservoir remaining amount to be reported (e.g., the insulin reservoir remaining may be reported at the same time as the bolus-delivered or basal-delivered measurements).

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The measurement represents the amount of insulin remaining in the reservoir. The unit for the insulin reservoir remaining is international units.

5.3.10 Insulin concentration

The insulin concentration measurement represents the concentration of insulin in the reservoir. Normally it is specified as the amount of insulin in international units per milliliter of insulin solution. For example, U100 designates an insulin concentration of 100 IU/mL of insulin solution.

The measurement represents the insulin concentration. The unit for the insulin concentration is international units per milliliter.

5.3.11 Insulin-to-carbohydrate ratio (I:CHO) profile settings

This represents the patient's I:CHO, which is the amount of carbohydrate covered or disposed of by a 1 IU of insulin.

Insulin pump devices may offer the option of storing multiple I:CHOs as a patient may have varying ratios specific to a time of day or type of meal. The unit for the I:CHO profile setting is grams.

NOTE—This object represents a device setting and not a measurement value.

5.3.12 Insulin sensitivity factor (ISF) profile settings

This represents the patient's ISF or sometimes referred to as a *correction factor*, which is an estimated amount of blood glucose reduced by a single unit of insulin.

Insulin pump devices may offer the option of storing multiple ISFs as a patient may have varying factors specific to the time of day. The unit for the ISF profile setting is millimole/liter or milligrams/deciliter.

NOTE—This object represents a device setting and not a measurement value.

5.3.13 Operational status

The *operational status* represents the operation and therapy conditions of the insulin pump device. Operational conditions are Off, Stand-By, Preparing, Priming, Waiting, Ready, and Undetermined. Therapy conditions are Pause, Stop, and Run.

5.3.14 PHD DM status

The *PHD DM status* allows generic notification handling for personal health devices. The status of the device is represented in a number of bit flags covering warning, error, service, and undetermined statuses. Changes in status are sent as events notifying the manager.

This represents a generic notification mechanism for a device to report warnings, errors, and other abnormal statuses to a manager that may provide visibility of these status change events to the user.

5.3.15 Insulin pump status

The *insulin pump status* represents the specific notifications given by the insulin pump for handling, warnings, errors, reminders, or confirmations to user-initiated events meant to provide visibility of events to the user and manufacture.

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5.4 Stored data

As stated in 5.3.1, an insulin pump may be used over several months of operation without being connected to a manager to send its data. Once an insulin pump is connected to a manager, the manager is able to select which of the agent's stored measurements or observations to retrieve. Depending on the agent's capabilities to organize its data into clusters of chronologically contiguous data, the manager may also select the time ranges of the stored data to retrieve. The agent then transmits the manager's selection in one or several blocks of messages for processing by a manager or other processing apparatus. The manager may also be able to choose a set of data clusters for deletion.

5.5 Scheduled data

An insulin pump may have the ability to program scheduled events such as basal profile settings, I:CHO profile settings, and ISF profile settings. These scheduled data provide information about the actions or events and time points that the actions or events occur. Once an insulin pump is connected to a manager, the manager is able to select which of the agent's scheduled data to retrieve. The agent then transmits the manager's selection in one or several blocks of messages for processing by a manager or other processing apparatus. The manager may also be able to choose a set of data clusters for deletion.

6. Insulin pump domain information model (DIM)

6.1 Overview

This clause describes the DIM of the insulin pump.

6.2 Class extensions

In this standard, extensions are defined with respect to ISO/IEEE 11073-20601:2016.

The following four attributes are an extension to the enumeration class.

— The Capability-Mask-Simple and Capability-Mask-Basic attributes indicate whether the corresponding bit in the Enum-Observed-Value-Simple-Bit-Str or Enum-Observed-Value-Basic-Bit-Str attribute, respectively, is supported by the Agent.

— The State-Flag-Simple and State-Flag-Basic attributes indicate whether the corresponding bit in the Enum-Observed-Value-Simple-Bit-Str or Enum-Observed-Value-Basic-Bit-Str attribute, respectively, is a state or event.

If the Enum-Observed-Value-Simple-Bit-Str attribute is used, the Capability-Mask-Simple and State-Flag-Simple attributes are mandatory. If the Enum-Observed-Value-Basic-Bit-Str attribute is used, the Capability-Mask-Basic and State-Flag-Basic attributes are mandatory. The values of the Capability-Mask-Simple, Capability-Mask-Basic, State-Flag-Simple, and State-Flag-Basic attributes are implementation specific.

See Annex B for their ASN.1 structures.

The Capability-Mask-Simple or Capability-Mask-Basic attribute is dynamic, i.e., the attribute may change at some point after configuration. The State-Flag-Simple or State-Flag-Basic attribute is static, i.e., the attribute shall remain unchanged after the configuration is agreed upon.

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6.3 Object instance diagram

The metric object instance diagram of the insulin pump DIM, defined for the purposes of this standard, is shown in Figure 4.

The objects of the DIM, as shown in Figure 4, include the medical device system (MDS) object (see 6.6), the numeric objects (see 6.7), the real-time sample array objects (see 6.8), the enumeration objects (see 6.9), the persistent metric–store (PM-store) objects (see 6.10), and the scanner objects (see 6.11). See 6.14 for rules for extending the insulin pump information model beyond elements as described in this standard. Each subclause that describes an object of the insulin pump contains the following information:

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

— The attributes of the object. Each object has attributes that represent and convey information on the physical device and its data sources. Each object has a handle attribute that identifies the object instance within an agent. Attribute values are accessed and modified using methods such as GET and SET. Attribute types are defined using ASN.1. The ASN.1 definitions for new attribute types specific to this standard are in Annex B, and the ASN.1 definitions for existing attribute types referenced in this standard are in ISO/IEEE 11073-20601:2016.

— The methods available on the object.

— The potential events generated by the object. The data are sent to the manager using events.

— The available services such as getting or setting attributes.

The attributes for each class are defined in tables that specify the name of the attribute, its value, and its qualifier. The qualifiers are defined as follows:

— M: attribute is mandatory.

— C: attribute is conditional and depends on the condition stated in the Remark or Value column (if ISO/IEEE 11073-20601:2016 is referenced, then it contains the conditions).

— R: attribute is recommended.

— NR: attribute is not recommended.

— O: attribute is optional.

Mandatory attributes shall be implemented by an agent. Conditional attributes shall be implemented if the condition applies and may be implemented otherwise. Recommended attributes should be implemented by the agent. Not recommended attributes should not be implemented by the agent. Optional attributes may be implemented by the agent. For attributes with qualifiers set to R or NR, underlying requirements stated in the Remark and Value column in ISO/IEEE 11073-20601:2016 shall be followed.

The attributes can be either static, i.e., they shall remain unchanged after the configuration is agreed upon, or dynamic, i.e., the attribute may change at some point after configuration.

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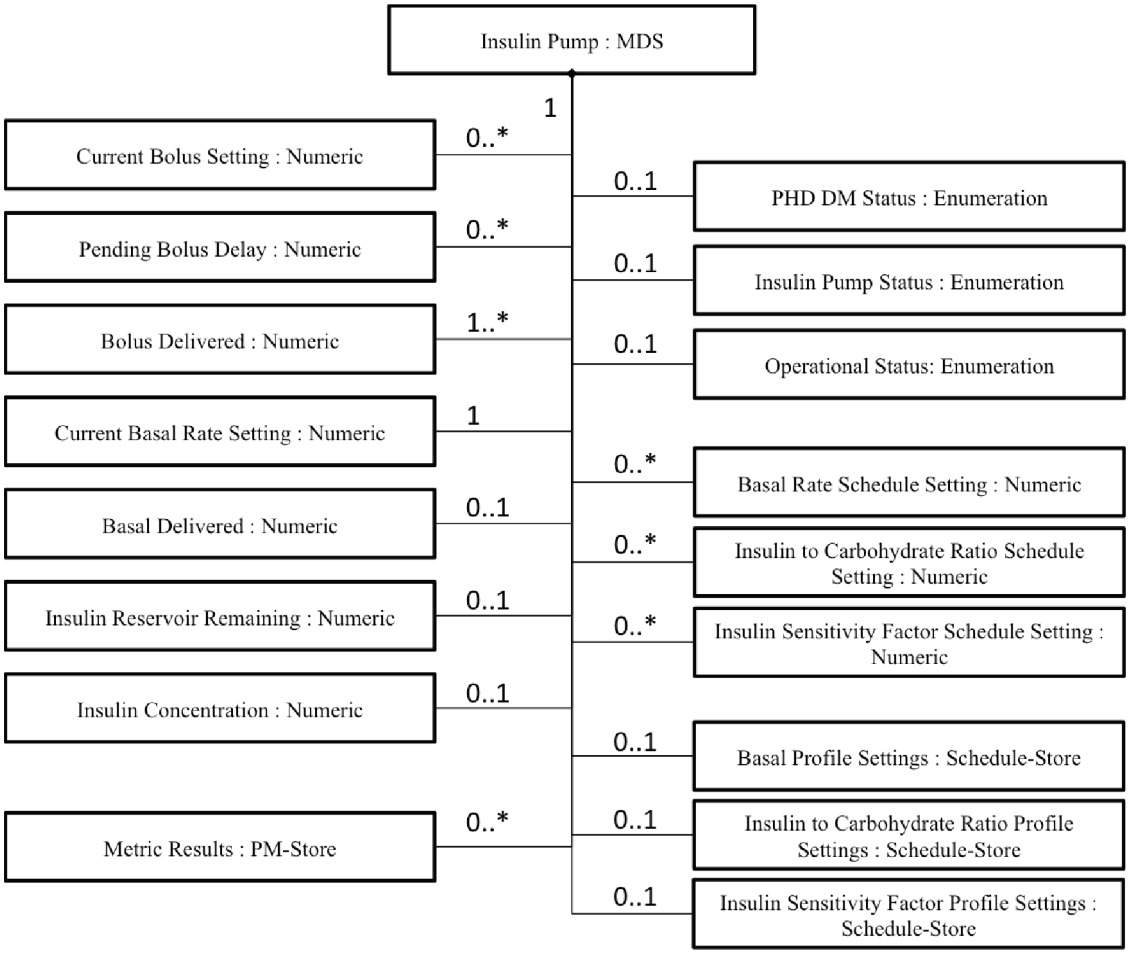


Figure 4—Insulin pump DIM

6.4 Types of configuration

6.4.1 General

As specified in ISO/IEEE 11073-20601:2016, there are two styles of configuration available. Subclauses 6.4.2 and 6.4.3 briefly introduce standard and extended configurations.

6.4.2 Standard configuration

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

One standard configuration is defined in this standard. The standard configuration 1900 (0x076C) contains one bolus delivered object (see 6.7.4) and one current basal rate setting object (see 6.7.5).

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6.4.3 Extended configuration

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

6.5 Profiles

6.5.1 General

A profile further constrains the objects, services, and communication model of a specialization. By profiling the device specialization, the standard provides more guidance on the specific mandatory objects that shall be implemented, the objects that are optional, and the objects that are not required. This standard does not define profiles for the insulin pump device.

6.6 MDS object

6.6.1 MDS object attributes

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

Table 1—MDS object attributes

Attribute name	Value	Qualifier
Handle	0	M
System-Type	Attribute not present. See ISO/IEEE 11073-20601:2016.	C
System-Type-Spec-List	{MDC_DEV_SPEC_PROFILE_INSULIN_PUMP, 2}.	M
System-Model	{"Manufacturer","Model"}	M
System-Id	Extended unique identifier (64-bits) (EUI-64)	M
Dev-Configuration-Id	Standard config: 0x076C (1900) Extended configs: 0x4000-0x7FFF	M
Attribute-Value-Map	See ISO/IEEE 11073-20601:2016.	C
Production-Specification	See ISO/IEEE 11073-20601:2016.	O
Mds-Time-Info	See ISO/IEEE 11073-20601:2016.	C
Date-and-Time	See ISO/IEEE 11073-20601:2016.	C
Base-Offset-Time	See ISO/IEEE 11073-20601:2016.	M
Relative-Time	See ISO/IEEE 11073-20601:2016.	C
HiRes-Relative-Time	See ISO/IEEE 11073-20601:2016.	C
Date-and-Time-Adjustment	See ISO/IEEE 11073-20601:2016.	C
Power-Status	See ISO/IEEE 11073-20601:2016.	R
Battery-Level	See ISO/IEEE 11073-20601:2016.	R
Remaining-Battery-Time	See ISO/IEEE 11073-20601:2016.	R
Reg-Cert-Data-List	See ISO/IEEE 11073-20601:2016.	O
Confirm-Timeout	See ISO/IEEE 11073-20601:2016.	O

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NOTE—See ISO/IEEE 11073-20601:2016 for information on whether an attribute is static or dynamic.

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

See ISO/IEEE 11073-20601:2016 for descriptive explanations of the individual attributes as well as for information on attribute ID and attribute type.

The Dev-Configuration-Id attribute holds a locally unique 16-bit identifier that identifies the device configuration. For an insulin pump agent with extended configuration, this identifier is chosen in the range of extended-config-start to extended-config-end (see ISO/IEEE 11073-20601:2016) as shown in Table 1.

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

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

6.6.2 MDS object methods

Table 2 defines the methods (actions) of the MDS object. These methods are invoked using the Action service. In Table 2, the Subservice type name column defines the name of the method; the Mode column defines whether the method is invoked as an unconfirmed action (i.e., roiv-cmip-action from ISO/IEEE 11073-20601:2016) or a confirmed action (i.e., roiv-cmip-confirmed-action); the Subservice type (action-type) column defines the nomenclature code to use in the action-type field of an action request and response (see ISO/IEEE 11073-20601:2016); the Parameters (action-info-args) column defines the associated ASN.1 data structure (see ISO/IEEE 11073-20601:2016 for ASN.1 definitions) to use in the action message for the action-info-args field of the request; and the Results (action-info-args) column defines the structure to use in the action-info-args of the response.

Table 2—MDS object methods

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

— **Set-Time:**

This method allows the manager to set a real-time clock in the agent with the absolute time. The agent indicates whether the Set-Time command is valid using the mds-time-capab-set-clock bit in the Mds-Time-Info attribute (see ISO/IEEE 11073-20601:2016).

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

— **Set-Base-Offset-Time:**

This method allows the manager to set a real-time clock in the agent with the base time and offset. The agent indicates whether the Set-Base-Offset-Time command is valid using the mds-time-capab-set-clock bit in the Mds-Time-Info attribute (see ISO/IEEE 11073-20601:2016).

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

Agents following only this device specialization and no others shall send event reports using agent-initiated measurement data transmission. Agents following this device specialization as well as others shall send

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event reports in the appropriate fashion. During the association procedure (see 8.3), data-req-mode-capab shall be set to the appropriate value for the event report style. As a result, the manager shall assume the insulin pump agent does not support any of the MDS-Data-Request features (see ISO/IEEE 11073-20601:2016 for additional information). Thus, implementation of the MDS-Data-Request method/action is not required in this standard and is not shown in Table 2.

6.6.3 MDS object events

Table 3 defines the events that can be sent by the insulin pump MDS object.

Table 3—Insulin pump MDS object events

Service	Subservice type name	Mode	Subservice type (event-type)	Parameters (event-info)	Results (event-reply-info)
EVENT REPORT	MDS-Configuration-Event	Confirmed	MDC_NOTI_CONFIG	ConfigReport	ConfigReport Rsp
	MDS-Dynamic-Data-Update-Var	Confirmed	MDC_NOTI_SCAN_REPORT_VAR	ScanReportInfoVar	—
	MDS-Dynamic-Data-Update-Fixed	Confirmed	MDC_NOTI_SCAN_REPORT_FIXED	ScanReportInfo Fixed	—
	MDS-Dynamic-Data-Update-MP-Var	Confirmed	MDC_NOTI_SCAN_REPORT_MP_VAR	ScanReportInfoMP Var	—
	MDS-Dynamic-Data-Update-MP-Fixed	Confirmed	MDC_NOTI_SCAN_REPORT_MP_FIXED	ScanReportInfoMP Fixed	—

— **MDS-Configuration-Event:**

This event is sent by the insulin pump agent during the configuring procedure if the manager does not already know the insulin pump agent's configuration from past associations or because the manager has not been implemented to recognize the configuration according to the insulin pump device specialization. The event provides static information about the supported measurement capabilities of the insulin pump agent.

— **MDS-Dynamic-Data-Update-Var:**

This event provides dynamic measurement data from the insulin pump agent for the numeric and enumeration objects. These data are reported using a generic attribute list variable format. The event is sent as an unsolicited message by the agent (i.e., an agent-initiated measurement data transmission). See 8.5.3 for more information on unsolicited event reporting.

— **MDS-Dynamic-Data-Update-Fixed:**

This event provides dynamic measurement data from the insulin pump agent for the numeric and enumeration objects. These data are reported in the fixed format defined by the Attribute-Value-Map attribute of the objects. The event is sent as an unsolicited message by the agent (i.e., an agent-initiated measurement data transmission). See 8.5.3 for more information on unsolicited event reporting.

— **MDS-Dynamic-Data-Update-MP-Var:**

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

— **MDS-Dynamic-Data-Update-MP-Fixed:**

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

NOTE—ISO/IEEE 11073-20601:2016 requires that managers support all of the MDS Object Events listed above.

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6.6.4 Other MDS services

6.6.4.1 GET service

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

The manager may request the MDS object attributes of the insulin pump agent; in which case, the manager shall send the "Remote Operation Invoke | Get" message (see roiv-cmip-get in ISO/IEEE 11073-20601:2016) with the reserved MDS handle value of 0. The insulin pump agent shall report its MDS object attributes to the manager using the "Remote Operation Response | Get" message (see rors-cmip-get in ISO/IEEE 11073-20601:2016). See Table 4 for a summary of the GET service including some message fields.

Table 4—Insulin pump MDS object GET service

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

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

6.6.4.2 SET service

The insulin pump specialization does not require an implementation to support the MDS object SET service.

6.7 Numeric objects

6.7.1 General

The insulin pump DIM for metric objects (see Figure 4) contains numeric objects that represent aspects of insulin delivery.

Sometimes, the interpretation of one attribute value in an object depends on other attribute values in the same object. For example, Unit-Code and Unit-LabelString provide context for the observed values. Whenever a contextual attribute changes, the agent shall report these changes to the manager using an MDS object event (see 6.6.3) prior to reporting any of the dependent values.

6.7.2 Current bolus setting

Table 5 summarizes the attributes of the current bolus setting numeric object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. The current bolus setting numeric object may be present in the extended configuration.

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Table 5—Current bolus setting numeric object attributes

Attribute name	Extended configuration	
	Value	Qualifier
Handle	See ISO/IEEE 11073-20601:2016.	M
Type	{MDC_PART_PHD_DM | MDC_INS_BOLUS_SET}	M
Supplemental-Types	See following text in Table 6.	R
Metric-Spec-Small	mss-avail-intermittent | mss-avail-stored-data | mss-upd-aperiodic | mss-acc-manager-initiated | mss-acc-agent-initiated | mss-cat-manual | mss-cat-setting | mss-cat-calculation	M
Metric-Structure-Small	See ISO/IEEE 11073-20601:2016.	O
Measurement-Status	See ISO/IEEE 11073-20601:2016.	O
Metric-Id	See following text in Table 7.	R
Metric-Id-List	See ISO/IEEE 11073-20601:2016.	O
Metric-Id-Partition	See ISO/IEEE 11073-20601:2016.	NR
Unit-Code	MDC_DIM_INTL_UNIT	M
Attribute-Value-Map	See ISO/IEEE 11073-20601:2016.	C
Source-Handle-Reference	See ISO/IEEE 11073-20601:2016.	NR
Label-String	See ISO/IEEE 11073-20601:2016.	O
Unit-LabelString	See ISO/IEEE 11073-20601:2016.	O
Absolute-Time-Stamp	See ISO/IEEE 11073-20601:2016.	C
Base-Offset-Time-Stamp	See ISO/IEEE 11073-20601:2016.	R
Relative-Time-Stamp	See ISO/IEEE 11073-20601:2016.	C
HiRes-Time-Stamp	See ISO/IEEE 11073-20601:2016.	C
Measure-Active-Period	See following text.	C
Simple-Nu-Observed-Value	See ISO/IEEE 11073-20601:2016.	C
Compound-Simple-Nu-Observed-Value	See ISO/IEEE 11073-20601:2016.	NR
Basic-Nu-Observed-Value	See ISO/IEEE 11073-20601:2016.	R
Compound-Basic-Nu-Observed-Value	See ISO/IEEE 11073-20601:2016.	C
Nu-Observed-Value	See ISO/IEEE 11073-20601:2016.	C
Compound-Nu-Observed-Value	See ISO/IEEE 11073-20601:2016.	C
Accuracy	See ISO/IEEE 11073-20601:2016.	NR

NOTE 1—See ISO/IEEE 11073-20601:2016 for information on whether an attribute is static or dynamic.

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

The value reported in this object is the amount of insulin requested to be delivered as a bolus and is reported before the pump delivers the bolus. Only non-negative numbers shall be used.

An insulin pump agent may contain multiple bolus setting objects if it is designed to transmit multiple modalities of bolus delivery, in which case the modality shall be denoted in the Supplemental-Type attribute.

The Supplemental-Types attribute is used to distinguish the modality and the reason for delivering a bolus of insulin. Table 6 represents the possible values to express a fast or extended bolus delivery mode as well as correction or meal bolus delivery reason.

Certain combinations of Supplemental-Types are allowed. If it is desired to express that a meal bolus was delivered as a fast bolus, the SupplementalTypesList structure of the Supplemental-Types attribute should contain the two values MDC_INS_BOLUS_MEAL and MDC_INS_BOLUS_FAST. Similarly, a correction bolus delivered as an extended bolus should contain MDC_INS_BOLUS_CORR and MDC_INS_BOLUS_EXT in the SupplementalTypesList.

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The modality values MDC_INS_BOLUS_FAST and MDC_INS_BOLUS_EXT shall not be combined in the SupplementalTypesList describing the bolus context. However, a multi-wave bolus modality may be represented by reporting separate current bolus setting objects with MDC_INS_BOLUS_FAST and MDC_INS_BOLUS_EXT at the same time.

If an acceptable, existing nomenclature term is not available, MDC_INS_BOLUS_UNDETERMINED shall be used.

Table 6—Bolus context

Type	Definition
MDC_INS_BOLUS_FAST	Bolus insulin delivered as fast bolus
MDC_INS_BOLUS_EXT	Bolus insulin delivered as an extended bolus
MDC_INS_BOLUS_CORR	Bolus insulin delivered for a correction
MDC_INS_BOLUS_MEAL	Bolus insulin delivered for a meal
MDC_INS_BOLUS_UNDETERMINED	Undetermined bolus

The Metric-ID attribute is used to distinguish the bolus setting source and described in Table 7.

If an acceptable, existing nomenclature term is not available, MDC_INS_BOLUS_OTHER shall be used.

Table 7—Bolus source

Type	Definition
MDC_INS_BOLUS_MANUAL	Manual, user defined bolus
MDC_INS_BOLUS_RECOMMENDED	Recommended bolus (e.g., bolus calculator)
MDC_INS_BOLUS_MANUAL_CHANGE	Recommended bolus changed by a user
MDC_INS_BOLUS_COMMANDED	Commanded bolus (e.g., artificial pancreas controller)
MDC_INS_BOLUS_OTHER	Other source of bolus

The Measure-Active-Period attribute shall be used with the MDC_INS_BOLUS_EXT to describe the time duration of the extended bolus setting.

The current bolus setting numeric object does not support any methods, events, or other services.

See ISO/IEEE 11073-20601:2016 for descriptive explanations on the individual attributes as well as for information on attribute ID and attribute type.

6.7.3 Pending bolus delay

Table 8 summarizes the attributes of the pending bolus delay numeric object. The nomenclature code to identify the numeric class is MDC_MOC_VMO_METRIC_NU. The pending bolus delay numeric object may be present in the extended configuration.

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