CENTER for MEDICAL INTEROPERABILITY

The Center for Medical Interoperability Specification Clinical Data Interoperability Based on IHE PCD – Semantics, Syntax and Encoding

C4MI-SP-CDI-IHE-PCD-SSE-I01-2019-09-27

Issued

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Work in Progress	An incomplete document designed to guide discussion and generate feedback that may include several alternative requirements for consideration.
Draft	A document considered largely complete but lacking review by Members and vendors. Drafts are susceptible to substantial change during the review process.
Issued	A public document that has undergone Member and Technology Supplier review, cross-vendor interoperability, and is for Certification testing if applicable. Issued Specifications are subject to the Engineering Change Process.
Closed	A static document, reviewed, tested, validated, and closed to further engineering change requests to the specification through The Center.

1 Scope

1.1 Introduction and Purpose

This document establishes an interface for medical devices, gateways, and other systems to exchange clinical data via IHE PCD transactions (which are based on HL7 v2.6 messages). The requirements herein establish standard syntax, semantics, and encoding for exchanged data and build on C4MI's foundational specifications for network connectivity and secure communications. This is a normative document, intended for designers and architects of medical devices and systems and for technical operations personnel from the healthcare provider community.

1.1.1 Clinical Motivation & Data Quality

The demand for Patient Care Device (PCD) data has increased post EHR deployment with enhanced clinician access, visualization, and utilization. Despite this, intensivists and clinicians describe an obfuscating flood of physiologic data in complex environments of care while engaging critically ill patients with an equally complex array of therapeutic options. By reducing the effort and error in mapping device data from multiple vendors into core systems, data quality is improved, visualization is enhanced, and data can be correlated and blended into coherent clinical pictures.

1.2 Requirements

Throughout this document, the key words "SHALL", "SHALL NOT", "SHOULD", "SHOULD NOT", and "MAY" in this document are to be interpreted as described in [IETF-RFC2119]:

"SHALL"	This word means that the item is an absolute requirement of this specification.
"SHALL NOT"	This phrase means that the item is an absolute prohibition of this specification.
"SHOULD"	This word means that there may exist valid reasons in particular circumstances to ignore this item, but the full implications should be understood and carefully weighed before choosing a different course.
"SHOULD NOT"	This phrase means that there may exist valid reasons in particular circumstances when the listed behavior is acceptable or even useful, but the full implications should be understood and the case carefully weighed before implementing any behavior described with this label.
"MAY"	This word means that an item is truly optional. One vendor may choose to include the item because a particular marketplace requires it or because it enhances the product while another vendor may omit the same item.

2 References

2.1 Normative References

In order to claim compliance with this specification, it is necessary to conform to the following standards and other works as indicated, in addition to the other requirements of this specification. Notwithstanding, intellectual property rights may be required to use or implement such normative references.

All references are subject to revision, and parties to agreement based on this specification are encouraged to investigate the possibility of applying the most recent editions of the documents listed below.

[FIPS-180-4] *Secure Hash Standard (SHS),* FIPS 180-4, August 2015.
Available: https://csrc.nist.gov/publications/detail/fips/180/4/final

[FIPS-186-4] *Digital Signature Standard (DSS),* FIPS 186-4, July 2013.
Available: https://csrc.nist.gov/publications/detail/fips/186/4/final

[HL7-V2.6] *Health Level Seven International HL7 V2.6.*
Available:
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=145

[HL7-V2.8.2-PRT] *HL7 Messaging Standard Version 2.8.2, Section 7.4.4 PRT – Participation Information Segment.*
Available:
http://www.hl7.org/implement/standards/product_brief.cfm?product_id=403

[IEEE-10101-2004] *Health informatics – Point-of-care medical device communication – Part 10101: Nomenclature*, ISO/IEEE 11073-10101-2004.
Available: http://standards.ieee.org/findstds/standard/11073-10101-2004.html
Defines a comprehensive vital signs nomenclature suitable for patient monitors, infusion pumps, anesthesia machines, ventilators, and other devices.

[IEEE-10101a-2015] *Health informatics – Point-of-care medical device communication – Part 10101: Nomenclature – Amendment 1: Additional Definitions,*
ISO/IEEE 11073-10101-2015.
Available: http://standards.ieee.org/findstds/standard/11073-10101a-2015.html
This is a significant extension to the ISO/IEEE 11073-10101:2004 base nomenclature standard, covering terminology for over a dozen medical devices, with a strong focus on respiratory, ventilators, and anesthesia.

[IETF-RFC2119] *Key words for use in RFCs to Indicate Requirement Levels,* RFC2119, March 1997.
Available: https://tools.ietf.org/html/rfc2119

[IETF-RFC2131] *Dynamic Host Configuration Protocol,* RFC2131, March 1997.
Available: https://tools.ietf.org/html/rfc2131

[IETF-RFC2132] *DHCP Options and BOOTP Vendor Extensions,* RFC2132, March 1977.
Available: https://tools.ietf.org/html/rfc2132

[IETF-RFC3315] *Dynamic Host Configuration Protocol for IPv6 (DHCPv6),* RFC3315, July 2003.
Available: https://tools.ietf.org/html/rfc3315

[IETF-RFC3646] *DNS Configuration options for Dynamic Host Configuration Protocol for IPv6 (DHCPv6),* RFC3646, December 2003.
Available: https://tools.ietf.org/html/rfc3646

[IETF-RFC4180] *Common Format and MIME Type for Comma-Separated Values (CSV) Files,* RFC4180, October 2005.
Available: https://tools.ietf.org/html/rfc4180

[IETF-RFC4704] *The Dynamic Host Configuration Protocol for IPv6 (DHCPv6) Client Fully Qualified Domain Name (FQDN) Option,* RFC4704, October 2006.
Available: https://tools.ietf.org/html/rfc4704

[IETF-RFC5246] *The Transport Layer Security (TLS) Protocol Version 1.2,* RFC5246, August 2008.
Available: https://tools.ietf.org/html/rfc5246

[IETF-RFC5280] *Internet X.509 Public Key Infrastructure Certificate and Certificate Revocation List (CRL) Profile,* RFC5280, May 2008.
Available: https://tools.ietf.org/html/rfc5280

[IETF-RFC5288] *AES Galois Counter Mode (GCM) Cipher Suites for TLS,* RFC5288, August 2008.
Available: https://tools.ietf.org/html/rfc5288

[IETF-RFC5289] *TLS Elliptic Curve Cipher Suites with SHA-256/384 and AES Galois Counter Mode (GCM),* RFC5289, August 2008.
Available: https://tools.ietf.org/html/rfc5289

[IETF-RFC5908] *Network Time Protocol (NTP) Server Option for DHCPv6,* RFC5908, June 2010.
Available: https://tools.ietf.org/html/rfc5908

[IETF-RFC6724] *Default Address Selection for Internet Protocol Version 6 (IPv6)*, RFC6724, September 2012.
Available: https://tools.ietf.org/html/rfc6724

[IETF-RFC6960] *X.509 Internet Public Key Infrastructure Online Certificate Status Protocol - OCSP,* RFC6960, June 2013.
Available: https://tools.ietf.org/html/rfc6960

[IETF-RFC8422] *Elliptic Curve Cryptography (ECC) Cipher Suites for Transport Layer Security (TLS) Versions 1.2 and Earlier,* RFC8422, August 2018.
Available: https://tools.ietf.org/html/rfc8422

[IHE-ITI-TF-1] *IHE IT Infrastructure (ITI) Technical Framework,* Volume 1 (ITI TF-1), July 2017.
Available:
http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf
The IHE IT Infrastructure Technical Framework identifies and specifies the subset of functional components and standards for sharing healthcare information across the healthcare enterprise. IHE PCD uses three ITI profiles: Consistent Time (CT), Patient Administration Management (PAM), and Patient Demographics Query (PDQ).

[IHE-ITI-TF-2a] *IHE IT Infrastructure (ITI) Technical Framework,* Volume 2a (ITI TF-2a), Integration Transactions Part A – Sections 3.1 – 3.28, July 2017.
Available:
http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol2a.pdf
Defines the mandatory 'Maintain Time' [ITI-1] transaction for the Consistent Time (CT) profile. Defines the 'Patient Demographics Query' [ITI-21] transaction (PDQ is less frequently used than PAM).

[IHE-PCD-TF-1] *IHE Patient Care Device (PCD) Technical Framework,* Volume 1, IHE PCD TF-1, October 2018.
Available: https://www.ihe.net/resources/technical_frameworks/#pcd

[IHE-PCD-TF-2] *IHE Patient Care Device (PCD) Technical Framework,* Volume 2, IHE PCD TF-2, October 2018.
Available: https://www.ihe.net/resources/technical_frameworks/#pcd

[NIST-hRTM] *NIST RTMMS 'Harmonized Rosetta'.*
Available: https://rtmms.nist.gov/rtmms/index.htm#!hrosetta
The Harmonized Rosetta contains 880+ IEEE 11073 terms with units, enums, and measurement-site co-constraints. Future iterations of this specification may reference a specific version of the hRTM.

[NIST-RTMMS] *NIST Rosetta Terminology Mapping Management System (RTMMS).*
Available: https://rtmms.nist.gov/

[UCUM] G. Shadow and C. McDonald, *The Unified Code for Units of Measure (UCUM)*, 2019.
Available: https://unitsofmeasure.org/

2.2 Informative References

This specification uses the following informative references:

[CC BY-SA 4.0] Some figures in C4MI specifications are presented under this Creative Commons License CC BY-SA 4.0.
Available: https://creativecommons.org/licenses/by-sa/4.0/legalcode

[CMI-DOC-TD] *The Center for Medical Interoperability Document: Terms and Definitions,* CMI-DOC-TD-D02-2019-05-31.
Available: https://medicalinteroperability.org/specifications/d02/

[CMI-SP-F-CP] *The Center for Medical Interoperability Specification: Certificate Policy,* CMI-SP-F-CP-D02-2019-05-31.
Available: https://medicalinteroperability.org/specifications/d02/

[IETF-BCP195] *Recommendations for Secure Use of Transport Layer Security (TLS) and Datagram Transport Layer Security (DTLS).*
Available: https://tools.ietf.org/html/bcp195

[IHE-PCD-TF-3] *IHE Patient Care Device (PCD) Technical Framework,* Volume 3, IHE PCD TF-3, October 2018.
Available: https://www.ihe.net/resources/technical_frameworks/#pcd

[LOINC] Regenstrief Institute, Inc., *LOINC*, 2019.
Available: https://loinc.org/

[NPatchett] Some figures in C4MI specifications are built on images created by this Wikimedia Commons user.
Available: https://commons.wikimedia.org/wiki/User:Npatchett

[SNOMED-CT] SNOMED International, "SNOMED Clinical Terms", *SNOMED*, 2019.
Available: http://www.snomed.org/snomed-ct/

2.3 Reference Acquisition

- Center for Medical Interoperability, 8 City Boulevard, Suite 203 | Nashville, TN 37209; Phone +1-615-257-6410; http://medicalinteroperability.org/
- Internet Engineering Task Force (IETF) Secretariat, 48377 Fremont Blvd., Suite 117, Fremont, California 94538, USA, Phone: +1-510-492-4080, Fax: +1-510-492-4001, http://www.ietf.org
- The Institute of Electrical and Electronics Engineers, Inc., 3 Park Avenue, New York, NY 10016-5997, USA Phone: +1-732-981-0060, Fax: +1-732-562-1571, http://standards.ieee.org/findstds/index.html
- Health Level Seven International, 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104, USA Phone: +1-734-677-7777, Fax: +1-734-677-6622, email: hq@HL7.org, http://www.hl7.org/
- International Organization for Standardization (ISO), ISO Central Secretariat, Chemin de Blandonnet 8, CP 401 - 1214 Vernier, Geneva, Switzerland, Phone: +41 22 749 01 11, Fax: +41 22 733 34 30, email: central@iso.org, http://www.iso.org

3 Terms and Definitions

This specification uses the terms and definitions in [CMI-DOC-TD]. Additional definitions related to the NIST approval status of IEEE 11073 terms include:

Term Approval Status	**Description**
Approved and published	Terms and codes from a balloted, approved, and published IEEE 11073 standard. *Example: 147842^MDC_ECG_HEART_RATE^MDC (non-zero code, MDC_ REFID)*
Provisional	Terms and codes that have been formally reviewed and approved by an IEEE 11073 or IHE PCD working group but have not yet gone through the entire IEEE balloting process. *Example: 68321^MDC_ATTR_SAMPLE_COUNT^MDC (non-zero code, MDC_ REFID)*
Proposed	Interim terms without numeric codes that have not gone through a formal review process, typically used for initial prototyping. *Example: 0^MDCX_ECG_QT_DISPERSION^MDC (zero code, MDCX_ REFID)*
Private	Vendor-defined proprietary terms with permanent 'private' code assignment. 192512^*MDCXYZ_EEG_COHERENCE_INDEX^MDC (upper 4K in partition 2)*
External	Terms from other nomenclatures such as LOINC or SNOMED.
Harmonized Rosetta ***aka hRTM*** ***aka harmonized***	The set of IEEE 11073 observation identifiers and other terms listed on the [NIST-RTMMS] Harmonized Rosetta 'hRTM' tab that specifies the 880+ most frequently reported physiologic data, technical status, and settings information. Normative co-constraints regarding units-of-measure, enumerated values, and measurement sites are also specified.

Future iterations of this specification will update these term approval statues to reflect the latest work of the IHE PCD community.

4 Abbreviations and Acronyms

This specification uses the following abbreviations and acronyms:

Acronym	Definition
AES	Advanced Encryption Standard
ASCII	American Standard Code for Information Interchange
CA	Certification Authority
CF_CODE 10	Context Free 32-bit code associated with REFID (OBX-3.1)
CF_UCODE 10	Context Free 32-bit code associated with Units of measure (OBX-6.1)
C4MI	Center for Medical Interoperability
CRL	Certificate Revocation List
CSV	Comma-Separated Values
DEC	Device to Enterprise Communication
DHCP	Dynamic Host Configuration Protocol
DHE	Ephemeral Diffie-Hellman
DNS	Domain Name System
DOC	Device Observation Consumer (IHE PCD DEC)
DOR	Device Observation Reporter (IHE PCD DEC)
ECC	Elliptic-curve cryptography
ECDHE	Elliptic-curve Ephemeral Diffie-Hellman
ECG	Electrocardiogram
EHR	Electronic Health Record
FQDN	Fully Qualified Domain Name
GCM	Galois Counter Mode

Acronym	Definition
HDO	Health Delivery Organization
HL7	Health Level Seven International
hRTM	Harmonized Rosetta
ICU	Intensive Care Unit
IEEE	Institute of Electrical and Electronics Engineers
IETF	Internet Engineering Task Force
IHE	Integrating the Healthcare Enterprise
IP	Internet Protocol
ITI	IT Infrastructure
MDC	Medical Device Communication (i.e. IEEE 11073 MDC code)
MDS	Medical Device System (IEEE 11073)
MLLP	Minimum Lower Layer Protocol (HL7)
NIST	National Institute of Standards and Technology
NTP	Network Time Protocol (IETF)
OCSP	Online Certificate Status Protocol
PCD	Patient Care Device (i.e. IHE PCD domain)
PKI	Public Key Infrastructure
PRT	Participation (Segment)
REFID	IEEE 11073 Reference ID (OBX-3.2)
RSA	Rivest-Shamir-Adleman
RTMMS	Rosetta Terminology Mapping Management System
TLS	Transport Layer Security
UCUM	Unified Code for Units of Measure (OBX-6.1)

Acronym	Definition
URL	Uniform Resource Locator
UTC	Coordinated Universal Time
UOM	Units of Measure (i.e. OBX-6.1 UOM_MDC or UOM_UCUM)
VMD	Virtual Medical Device (IEEE 11073)

5 Overview

5.1 Architecture

Within C4MI's platform architecture, this specification establishes an interface for Connected Components such as Medical Devices and Gateways to report clinical data. While the specification's scope is currently limited to *reporting* data over this interface, future iterations may include requirements on data *consumers*.

The IHE PCD 'Device to Enterprise Communication' (DEC) profile defines the 'Communicate Device Data' (PCD-01) transaction as involving two actors - a 'Device Observation Reporter' (DOR) that sends clinical data such as vital signs, and a 'Device Observation Consumer' (DOC) that receives the data. This specification leverages IHE PCD by requiring that connected components report clinical data as an IHE PCD DOR.

The diagram below shows three example scenarios in which Connected Components communicate via this interface. (This diagram is not exhaustive, and other scenarios are possible.) The first scenario shows proprietary or standardized data from one or more Medical Devices going through a Gateway that translates and/or forwards it using the PCD-01 transaction. In this scenario, the Gateway is acting as the DOR, and the data exchange between the Medical Device and the Gateway is not in the scope of this specification. The second scenario shows a Medical Device sending its data directly to a Platform Service using the PCD-01 transaction. In this scenario, the Medical Device is acting as the DOR. The third scenario is currently out of scope, although future iterations to this specification may support Medical Devices and Gateways acting as a DOC. (While Medical Devices, Gateways, and Platform Services are all Connected Components, the requirements in this specification apply only to Connected Component that *report* clinical data using this interface.)

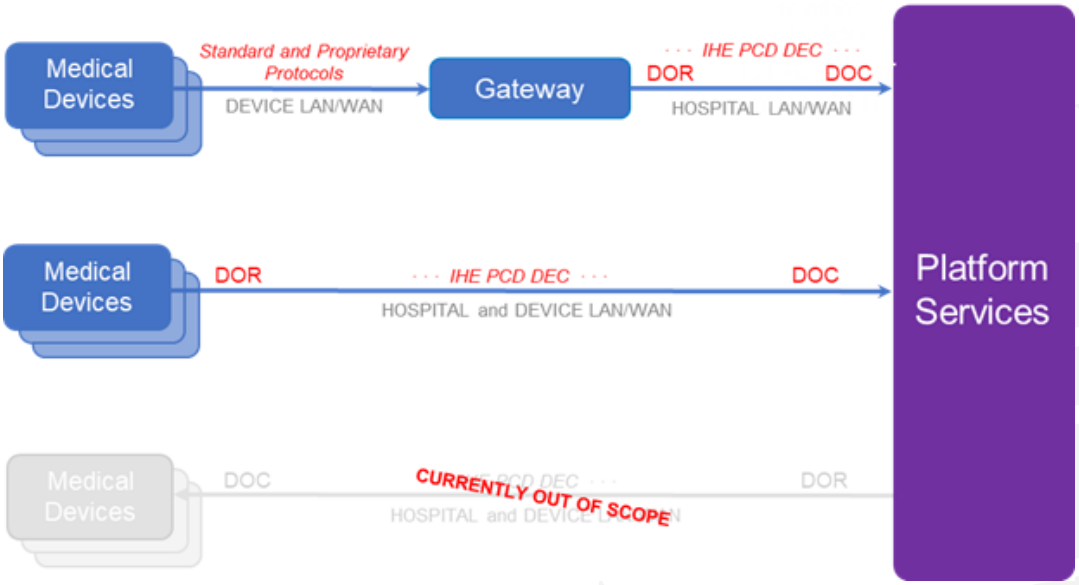


Figure 1. Connected Components communicating via the interface defined in this specification

6 Device Observation Reporter Requirements

6.1 Introduction

This section includes syntax, semantic, and encoding requirements on Connected Components that report clinical data using this interface. As a precondition for using this interface, Connected Components must first establish IP network connectivity and secure connections. Specific requirements for this precondition, including network access, certificate-based mutual authentication via TLS, and message encryption, are defined in annexes to this specification.

NOTE: In future iterations, these requirements may be in separate specifications instead of annexes to this specification.

Many requirements in this section leverage the "Integrating the Healthcare Enterprise" (IHE) Patient Care Device (PCD) technical Framework [IHE-PCD-TF-1] [IHE-PCD-TF-2]. Specifically, a Connected Component reporting data via this interface acts as a Device Observation Reporter (DOR) in the Device Enterprise Communication (DEC) profile, exchanging data via PCD Data (PCD-01) transactions. As such, this specification includes requirements on "the DOR", referring to any Connected Component reporting clinical data using this interface.

Generally, IHE PCD DEC transactions leverage HL7 V2.6 messages and the IEEE 11073-10101 medical device nomenclature. This specification further constrains DORs by requiring adherence to the Harmonized Rosetta terminology [NIST-hRTM], which provides additional semantic constraints, such as which units can be used for a reported medical device observation. (The Rosetta Terminology is hosted on the Rosetta Terminology Mapping Management System (RTMMS) [NIST-RTMMS], which is supported and hosted by NIST and is used for the development and curation of new terms, principally by the IEEE 11073 community.)

Value Sets defined in Annexes to this specification group concepts typically supported by certain connected component classes and identifies the Harmonized Rosetta identifiers required to convey those concepts. For example, the Physiological Monitoring Value Set includes concepts for data typically produced by patient monitoring devices, such as blood pressure. Where clarity or disambiguation is needed beyond the documentation available in IEEE 11073 and Harmonized Rosetta, Value Sets include additional descriptions or restrictions on allowable Harmonized Rosetta identifiers. In some cases, Value Sets also specify a preference in the case of true (non-synonymous) duplication or disambiguate in the case of co-option. The Center intends to propose these clarifications and restrictions for inclusion in Harmonized Rosetta.

NOTE: Future iterations of this specification will likely provide a mechanism for Connected Components to report or be queried for the Value Sets they support

The Harmonized Rosetta terminology defines a term approval process, under which terms may have varying "term approval status" such as "Approved and Published" or "Private". Table 1 shows example terms with varying approval statuses. Several requirements in this section refer to these statuses.

NOTE: These requirements may be modified in future iterations of this specification to support updates to the approval process as defined by the IHE PCD community.

Table 1. Examples of Terms with Varying Approval Statuses

Approved and published	147842^MDC_ECG_HEART_RATE^MDC
Provisional	68321^MDC_ATTR_SAMPLE_COUNT^MDC
Private	192512^MDCXYZ_EEG_COHERENCE_INDEX^MDC *(upper 4K of partition 2)*

6.2 DOR Secure Transport Requirement

The DOR SHALL comply with all requirements of the Secure Transport Annex. When configured with certificates, the DOR SHALL use the methods expressed in the Secure Transport Annex to establish an encrypted connection to the receiving application.

6.3 Messages

6.3.1 Connected Component IHE PCD DEC DOR Requirement

A Connected Component reporting clinical data over the interface defined in this specification SHALL comply with [IHE-PCD-TF-1] and [IHE-PCD-TF-2], acting as a Device Observation Reporter (DOR) in the Device Enterprise Communication (DEC) Profile, using the default MLLP Transport Option.

6.3.2 Syntax

6.3.2.1 DOR Message Syntax Requirement

Messages sent by the DOR SHALL comply with [HL7-V2.6] messaging syntax as constrained by [IHE-PCD-TF-2].

6.3.2.2 DOR Message PRT Segment Syntax Requirement

If the HL7 V2.8 'PRT' segment is sent, the message syntax SHALL comply with [HL7-V2.8.2-PRT] as constrained by [IHE-PCD-TF-2].

6.3.3 Observations

6.3.3.1 DOR Message Primary Observation Identifier Requirement

The primary OBX-3 (.1, .2, .3) identifier in any message sent by the DOR SHALL be from the first resource listed below that has an term appropriate for the message's content:

1. terms included in a Value Set defined in this specification that are not marked "deprecated" (see 'DOR Message Value Set Requirement')

2. 'approved and published' terms from the Harmonized Rosetta [NIST-hRTM] that are not included in a Value Set
3. 'provisional' terms from the Harmonized Rosetta [NIST-hRTM]
4. non-deprecated terms from a published IEEE 11073-10101 standard [IEEE-10101-2004] [IEEE-10101a-2015]
5. 'private' or 'proposed' terms (see 'DOR Message Private Term Usage Requirement')

6.3.3.2 DOR Message Value Set Requirement

Value Sets defined in Annexes to this specification clarify which Harmonized Rosetta identifiers correspond to certain clinical concepts.

1. When reporting a concept that is described in the “Common Term” and “Description/Disambiguation” columns of any Value Set, the corresponding Harmonized Rosetta identifier SHALL be used.
2. When reporting a concept for which two REFIDs are marked as “True Synonyms,” if a DOR reports REFIDs then the first listed REFID SHOULD be used and the second (italicized) MAY be used.
3. DORs SHALL NOT report REFIDs that are marked as “Recommended for Deprecation” in the C4MI Status column. Currently, the concepts conveyed with these REFIDs often vary between vendors, leading to semantic ambiguity. More specific concepts and their associated REFIDs are called out in Value Sets and are available in Harmonized Rosetta and IEEE 11073.

6.3.3.3 DOR Message Private Term Usage Requirement

DORs MAY send ‘private’ terms if no suitable standardized term exists (see 'DOR Message Primary Observation Identifier Requirement'). C4MI recognizes that while some concepts are valuable if standardized, others would provide little value to the larger community, such as an internal voltage reading of a medical device. In these cases, the use of ‘private’ terms is legitimate and encouraged. Because the industry evolves and innovations eventually become ubiquitous, DOR vendors are encouraged to periodically reassess their use of ‘private’ terms. In the interest of defining novel clinical concepts with the highest precision to support the larger community, DOR vendors SHOULD submit private terms to the hRTM for standardization and approval. Upon subsequent approval and publication to hRTM the vendor SHOULD notify C4MI as a prelude to consideration for addition to a C4MI value set.

NOTE: The 'DOR Disclosure Requirement' requires that all terms, including those terms designated ‘private’ and ‘proposed’, be disclosed along with their full description and associated units, enumerated values, etc.

6.3.3.4 DOR Message Private Term REFID Requirement

If a DOR sends a 'private' term, the message SHALL include its REFID in OBX-3.2 in addition to the mandatory OBX-3.1 numeric code. The private term's REFID SHALL indicate a namespace using the MDC*XXX*_ 'prefix' notation, where '*XXX*' is a string (of any length) that uniquely identifies the vendor

or other party responsible for defining the term. (See Table 1) In all cases, OBX-3.3 SHALL be 'MDC' and SHALL NOT be used to indicate a namespace or term approval status.

6.3.3.5 DOR Message hRTM Deprecated Terms Requirement

The primary OBX-3 (.1, .2, .3) identifier in any message sent by the DOR SHALL NOT be a 'deprecated' term from the Harmonized Rosetta.

6.3.3.6 DOR Message REFID Synonym Requirement

REFID-synonyms that have the same CF_CODE10 have been defined for several IEEE 11073 terms in the [NIST-RTMMS]; the first-listed REFID is preferred and SHOULD be used and the second-listed REFID is the less-preferred alternative and MAY be used.

6.3.3.7 DOR Message External Nomenclature Requirement

Messages sent by the DOR MAY use observation identifiers and other terms from external nomenclatures such as [LOINC] or [SNOMED-CT] as an alternative OBX-3 (.4,.5,.6) identifier.

6.3.3.8 DOR Message Semantic Accuracy Requirement

The semantics of a message SHALL be accurately reflected in the message's constructs (i.e. observation identifiers, units-of-measure, enumerated values, observation sites, and containment hierarchies) and their accompanying descriptions and documentation.

6.3.4 Co-Constraints

6.3.4.1 DOR Message Co-constraints Requirement

A message sent by a DOR that uses a term from the Harmonized Rosetta [NIST-hRTM] as its primary OBX-3 identifier:

1. SHALL convey a unit-of-measure from the hRTM UOM_MDC and/or UOM_UCUM [UCUM] columns in OBX 6 if and only if any are listed for the term-row specified by OBX-3
2. SHALL convey one or more enumerated value(s) from the hRTM Enum_Value column in OBX-5 if and only if any are listed for the term-row specified by OBX-3
3. SHALL convey one or more measurement site(s) from the hRTM External_Sites column in OBX-20 if and only if any are listed for the term-row specified by OBX-3, and this information is available on the device (e.g. entered via user interface)
4. SHOULD utilize a containment hierarchy as specified in [IHE-PCD-TF-3].

6.4 Capability Disclosure

To share their DOR's capabilities, DOR vendors disclose the IHE PCD DEC PCD-01 messages they support, including numeric observations and settings identifiers, units-of-measure, enumerated values, measurement sites, and containment hierarchies. This provides a human-readable capability summary, but its standardized format also lends it for use in automated testing, systems integration, and run-time semantic negotiation.

A DOR disclosure can describe the capabilities of a *single component* participating as a DOR, including its containment hierarchy, observation identifiers, and co-constraints. It can also document when a *set* of values are available, such as the user choice of cm[H2O] and kPa units of measure for airway pressure or when there is a choice of one or more enumerated values or measurement sites.

A DOR disclosure can also describe the *union of capabilities of multiple like-kind components*, provided that they have reasonably similar content models. For example, a single comprehensive model for a simple vital signs monitor could be used to consolidate data from multiple models and vendor designs before exporting it using a gateway. Otherwise, multiple disclosures for individual vendor and models would be required.

6.4.1 DOR Disclosure Requirement

DOR vendors SHALL disclose all of a DOR's reported observations, including 'private' and 'proposed' terms. The disclosure SHALL use the format defined in DOR Disclosure. Disclosed 'private' and 'proposed' terms SHALL have reasonably complete descriptions.

6.4.2 DOR "Demo" Mode Requirement

DOR vendors SHALL provide a "send-all" or "demo" mode in which the DOR sends all possible reported observation messages. DORs SHOULD use a DEMO MeasurementStatus (as defined in [IHE-PCD-TF-2]) to indicate the data is being sent for this purpose.

6.5 Time

6.5.1 DOR Consistent Time Requirement

The DOR SHALL maintain 'consistent time' with respect to an external NTP reference clock to within a median accuracy of ±1 second using the 'Maintain Time' (ITI-1) transaction [IHE-ITI-TF-2a] of the Consistent Time (CT) profile [IHE-ITI-TF-1].

Note: Future iterations of this specification may require timestamping at a higher resolution than 1 second.

6.5.2 DOR Obtaining Time Reference Requirement

The DOR SHALL comply with all requirements in Provisioning to enable plug-and-play time synchronization on properly configured networks.

6.5.3 DOR Time Zone Offset Requirement

Any message sent by the DOR SHALL include the time zone offset +/- ZZZZ with the distinction between +0000 (local time zone offset is known) or -0000 (local time zone offset is unknown but UTC time is known).

6.5.4 DOR Observation Timestamp Requirement

Timestamp values reported in OBR-7, OBR-8 and OBX-14 SHALL indicate the time that the original observation was made, not the time the message was sent or the data was later cached, archived or sent in response to a query.

Appendix I DOR Disclosure

I.1 Format

This Appendix defines the contents and format of a DOR disclosure. The disclosure uses a format similar to the [NIST-RTMMS] and [NIST-hRTM] with the exception that the REFID conveyed by OBX-3.2 is prefaced by zero or more dots to indicate its containment depth. Examples are provided in sections I.2 and I.3.

A DOR disclosure is an [IETF-RFC4180]-compliant CSV file, where each record corresponds to a reported observation. (RFC 4180 uses the term "record" to denote a "row" in a CSV file.) The CSV file uses a US-ASCII character set and includes a header line; the contents of each column is named (in order) and described in Table 2.

Containment hierarchies are disclosed via ordered records. A record disclosing an MDS term indicates that all subsequent records are within the scope of that MDS (until another MDS record is defined); a record disclosing a VMD term indicates that all subsequent records are within the scope of that VMD (until another VMD record is defined); and a record disclosing a CHAN term indicates that all subsequent records are within the scope of that CHAN (until another CHAN record is defined). All VMD, CHAN, and METRIC REFIDs are preceded with one, two, and three '.' characters, respectively. The METRIC 'dot-level 4' conveys the primary physiologic and device status information; the FACET 'dot-level 5' is used to convey additional attributes that further define or refine the parent METRIC value.

In general, the DOR disclosure includes all reported observation data, and so all columns must be nonempty, with the following exceptions:

- DORs are not required to report both MDC and UCUM units-of-measure, but if they do, then the order of the UOM_MDC and UOM_UCUM columns' lists align, using empty lines if necessary.
- A DOR disclosure must include any Enum_Values or External_Sites reported, although DORs are not required to report Enum_Values or External_Sites unless the observation requires them as defined in [hRTM].
- The Description column is only required for private terms, and is optional for other terms.

The phrase "multi-line list" is used throughout Table 2 to refer to a list of items delimited by a carriage return and line feed ('\r\n').

Table 2. DOR Disclosure Content

Column Name	Description
REFID	IEEE 11073 Reference ID(s) corresponding to the observation. Multiple Reference IDs in a multi-line list indicate synonymous REFIDs.
Description	Description associated with the REFID(s). *This column is required for private terms, but can be empty for other terms.*
CF_CODE10	Context-free 32-bit code associated with REFID (OBX-3.1)
UOM_MDC	IEEE 11073 MDC units-of-measure Reference ID (OBX-6.2) Multiple Reference IDs in a multi-line list indicate alternate units-of-measure are reported.
UOM_UCUM	UCUM units-of-measure (OBX-6.1) Multiple Reference IDs in a multi-line list indicate alternate units-of-measure are reported. If both MDC and UCUM units-of-measure are reported, then the order of the two columns' lists align, using empty lines if necessary. On each line, a space-delimited list indicates synonymous UCUM units are reported.
CF_UCODE10	Context-free 32-bit code associated with MDC units-of-measure (OBX-6.1) If the UOM_MDC column contains a multi-line list, this column contains a corresponding list whose order aligns with the UOM_MDC column, using empty lines if necessary.
Enum_Values	Enumerated values (OBX-5) A multi-line list indicates multiple possibilities for reported enumerated values. On each line, a space-delimited list indicates synonymous Enum_Values are reported.
External_Sites	External Site identifier(s) (OBX-20) A multi-line list indicates multiple possibilities for reported external sites. On each line, a space-delimited list indicates synonymous External_Sites are reported.

I.2 Simple Vital Signs Monitor (Informative)

Example DOR disclosures for a simple vital signs monitor are shown below using a tabular format with colors added for clarity.

The example shown in Table 3 is appropriate for a gateway that can send data for a variety of vital signs monitors made by multiple vendors. For example, multiple units of measure are listed to reflect the capabilities of all of the devices 'behind' the gateway and not just a specific device vendor and model. This includes the use of *either* IEEE 11073 MDC or UCUM units of measure.

The example shown in Table 4 is for a *specific device model and manufacturer*, listing only units of measure sent by the device. The CHAN OBX segments have also been removed for brevity, an optimization that is permitted by IHE PCD DEC when there is no loss of semantic context for the METRIC-level observations.

Table 3. DOR Disclosure Example - Vital Signs Monitor (multi-vendor with channels and all unit-of-measure options)

REFID	Description	CF_CODE10	UOM_MDC	UOM_UCUM	CF_UCODE10	Enum_Values	External_Sites
MDC_DEV_SYS_VS_MDS	Vital Signs Monitor	70741	.	.	.	.	.
. MDC_DEV_ANALY_SAT_O2_VMD	Pulse Oximetry (VMD)	69642	.	.	.	.	.
. . MDC_DEV_ANALY_SAT_O2_CHAN	SpO2 (Channel)	69643	.	.	.	.	.
. . . MDC_PULS_OXIM_SAT_O2	SpO2	150456	MDC_DIM_PERCENT	%	262688	.	.
. . . MDC_PULS_OXIM_PULS_RATE	SpO2 Pulse Rate	149530	MDC_DIM_BEAT_PER_MIN	{beat}/min	264864	.	.
. MDC_DEV_ECG_VMD	ECG (VMD)	69798	.	.	.	.	.
. . MDC_DEV_CARD_RATE_CHAN	ECG Heart Rate (Channel)	70739	.	.	.	.	.
. . . MDC_ECG_CARD_BEAT_RATE	ECG Heart Rate	147842	MDC_DIM_BEAT_PER_MIN	{beat}/min	264864	.	.
. MDC_DEV_ANALY_RESP_RATE_VMD	Resp (VMD)	69722	.	.	.	.	.
. . MDC_DEV_ANALY_RESP_RATE_CHAN	Resp Rate (Channel)	69723	.	.	.	.	.
. . . MDC_RESP_RATE	Resp Rate	151562	MDC_DIM_RESP_PER_MIN	{resp}/min	264928	.	.
. MDC_DEV_PRESS_BLD_NONINV_VMD	NIBP (VMD)	70686	.	.	.	.	.
. . MDC_DEV_PRESS_BLD_NONINV_CHAN	Systolic/Diastolic/MAP/Rate	70687	.	.	.	.	.
. . . MDC_PRESS_BLD_NONINV_SYS	Systolic	150021	MDC_DIM_MMHG MDC_DIM_KILO_PASCAL	mm[Hg] kPa	266016 265987	.	.
. . . MDC_PRESS_BLD_NONINV_DIA	Diastolic	150022	MDC_DIM_MMHG MDC_DIM_KILO_PASCAL	mm[Hg] kPa	266016 265987	.	.
. . . MDC_PRESS_BLD_NONINV_MEAN	Mean Arterial Pressure	150023	MDC_DIM_MMHG MDC_DIM_KILO_PASCAL	mm[Hg] kPa	266016 265987	.	.
. . . MDC_PULS_RATE_NON_INV	Pulse Rate	149546	MDC_DIM_BEAT_PER_MIN MDC_DIM_PER_MIN MDC_DIM_PULS_PER_MIN	{beat}/min {count}/min {pulse}/min	264864 264672 264896	.	.
. MDC_DEV_METER_TEMP_VMD	Temperature (VMD)	69902	.	.	.	.	.
. . MDC_DEV_METER_TEMP_CHAN	Body Temp (Channel)	69903	.	.	.	.	.
. . . MDC_TEMP_BODY	Body temperature	150364	MDC_DIM_DEGC MDC_DIM_FAHR	Cel [degF]	268192 266560	.	.

Table 4. DOR Disclosure Example - Vital Signs Monitor (single vendor, MDC units-of-measure, no channels)

REFID	CF_CODE10	UOM_MDC	UOM_UCUM	CF_UCODE10	Enum_Values	External_Sites
MDC_DEV_SYS_VS_MDS	70741	.	.	.	.	.
. MDC_DEV_ANALY_SAT_O2_VMD	69642	.	.	.	.	.
. . . MDC_PULS_OXIM_SAT_O2	150456	MDC_DIM_PERCENT	.	262688	.	.
. . . MDC_PULS_OXIM_PULS_RATE	149530	MDC_DIM_BEAT_PER_MIN	.	264864	.	.
. MDC_DEV_ECG_VMD	69798	.	.	.	.	.
. . . MDC_ECG_CARD_BEAT_RATE	147842	MDC_DIM_BEAT_PER_MIN	.	264864	.	.
. MDC_DEV_ANALY_RESP_RATE_VMD	69722	.	.	.	.	.
. . . MDC_RESP_RATE	151562	MDC_DIM_RESP_PER_MIN	.	264928	.	.
. MDC_DEV_PRESS_BLD_NONINV_VMD	70686	.	.	.	.	.
. . . MDC_PRESS_BLD_NONINV_SYS	150021	MDC_DIM_MMHG	.	266016	.	.
. . . MDC_PRESS_BLD_NONINV_DIA	150022	MDC_DIM_MMHG	.	266016	.	.
. . . MDC_PRESS_BLD_NONINV_MEAN	150023	MDC_DIM_MMHG	.	266016	.	.
. . . MDC_PULS_RATE_NON_INV	149546	MDC_DIM_PULS_PER_MIN	.	264896	.	.
MDC_DEV_METER_TEMP_VMD	69902	.	.	.	.	.
. . . MDC_TEMP_BODY	150364	MDC_DIM_DEGC MDC_DIM_FAHR	.	268192 266560	.	.

I.3 Infant Incubator or Warmer (Informative)

The DOR disclosure in Table 5 is for a combined infant incubator and/or warmer, aka microenvironment. It supports reporting temperature using °F and °C, and lists the enumerated values that represent the union of capabilities for at least two device vendors, multiple device types (incubator and/or warmer), and models.

An important addition to this disclosure is the listing of enumerated values, e.g. the microenvironment bed state MDC_MICROENV_BED_STATE is { BED_OPEN, BED_PARTIALLY_OPEN, BED_CLOSED }. Agreement regarding enumerated values is just as critical to interoperability as observation identifiers and units of measure.

This example also illustrates the necessity of MDC_DEV_INFANT_MICROENV_HEATER_RADIANT_CHAN and MDC_DEV_INFANT_MICROENV_HEATER_CONVECTIVE_CHAN to disambiguate (the four) common metric and setting values conveyed by both channels.

Table 5. Infant Incubator or Warmer (multi-vendor with channels, units-of-measure and enumerations)

REFID	CF_CODE10	UOM_MDC	UOM_UCUM	CF_UCODE10	Enum_Values	External_Sites
MDC_DEV_INFANT_MICROENV_MDS	70825	.	.	.	.	.
. MDC_DEV_INFANT_MICROENV_VMD	70826	.	.	.	.	.
. . MDC_DEV_INFANT_MICROENV_CHAN	70827	.	.	.	.	.
. . . MDC_MICROENV_TYPE	184336	.	.	.	OPEN	.
					CLOSED	
					COMBINATION	
. . . MDC_MICROENV_BED_STATE	184338	.	.	.	BED_OPEN	.
					BED_PARTIALLY_OPEN	
					BED_CLOSED	
. . . MDC_MICROENV_AIR_CURTAIN_STATE	184339	.	.	.	AIR_CURTAIN_OFF	.
					AIR_CURTAIN_ON	
					AIR_CURTAIN_USER_DISABLED	
. . . MDC_MICROENV_FAN_SPEED	184341	.	.	.	FAN_SPEED_LOW	.
					FAN_SPEED_HIGH	
. . MDC_DEV_INFANT_MICROENV_TEMP_PATIENT_CHAN	70835	.	.	.	.	.
. . . MDC_TEMP_SKIN	150388	MDC_DIM_DEGC	Cel	268192	.	.
		MDC_DIM_FAHR	[degF]	266560		
. . . MDC_TEMP_SKIN_SETTING	16927604	MDC_DIM_DEGC	Cel	268192	.	.
		MDC_DIM_FAHR	[degF]	266560		
. . MDC_DEV_INFANT_MICROENV_HEATER_RADIANT_CHAN	70843	.	.	.	.	.
. . . MDC_TEMP_MICROENV	184296	MDC_DIM_DEGC	Cel	268192	.	.
		MDC_DIM_FAHR	[degF]	266560		
. . . MDC_TEMP_MICROENV_SETTING	16961512	MDC_DIM_DEGC	Cel	268192	.	.
		MDC_DIM_FAHR	[degF]	266560		
. . . MDC_MICROENV_HEATER_TYPE	184337	.	.	.	RADIANT	.
					NONE	
. . . MDC_MICROENV_HEATER_CNTRL_MODE	184340	.	.	.	PATIENT	.
					AIR	
					MANUAL	
. . MDC_DEV_INFANT_MICROENV_HEATER_CONVECTIVE_CHAN	70839	.	.	.	.	.
. . . MDC_TEMP_MICROENV	184296	MDC_DIM_DEGC	Cel	268192	.	.
		MDC_DIM_FAHR	[degF]	266560		
. . . MDC_TEMP_MICROENV_SETTING	16961512	MDC_DIM_DEGC	Cel	268192	.	.

REFID	CF_CODE10	UOM_MDC	UOM_UCUM	CF_UCODE10	Enum_Values	External_Sites
		MDC_DIM_FAHR	[degF]	266560		
. . . MDC_MICROENV_HEATER_TYPE	184337	.	.	.	RADIANT	.
					CONVECTIVE	
					NONE	
. . . MDC_MICROENV_HEATER_HEAT_SINK_TEMP	184308	MDC_DIM_DEGC	Cel	268192	.	.
		MDC_DIM_FAHR	[degF]	266560		
. . . MDC_MICROENV_HEATER_HEAT_SINK_RESIST	184304	MDC_DIM_OHM	Ohm	266432	.	.
. . . MDC_MICROENV_HEATER_APPLIED_PWR	184300	MDC_DIM_PERCENT	%	262688	.	,
		MDC_DIM_WATT	W	266176		
. . . MDC_MICROENV_HEATER_CNTRL_MODE	184340	.	.	.	PATIENT	.
					AIR	
					MANUAL	
. . MDC_DEV_INFANT_MICROENV_HUMIDITY_CHAN	0	.	.	.	.	.
. . . MDC_REL_HUMIDITY_MICROENV	184292	MDC_DIM_PERCENT	%	262688	.	.
. . . MDC_REL_HUMIDITY_MICROENV_SETTING	16961508	MDC_DIM_PERCENT	%	262688	.	.
. . MDC_DEV_INFANT_MICROENV_O2_CHAN	0	.	.	.	.	.
. . . MDC_CONC_O2_MICROENV	184288	MDC_DIM_PERCENT	%	262688	.	.
. . . MDC_CONC_O2_MICROENV_SETTING	16961504	MDC_DIM_PERCENT	%	262688	.	.
. . MDC_DEV_CHAN	69635	.	.	.	.	.
. . . MDC_ATTR_PT_WEIGHT_LAST	188792	MDC_DIM_G	g	263872	.	.
. MDC_DEV_ANALY_SAT_O2_VMD	69642	.	.	.	.	.
. . MDC_DEV_ANALY_SAT_O2_CHAN	69643	.	.	.	.	.
. . . MDC_PULS_OXIM_SAT_O2	150456	MDC_DIM_PERCENT	%	262688	.	.
. . . MDC_PULS_OXIM_PULS_RATE	149530	MDC_DIM_BEAT_PER_MIN	{beat}/min	264864	.	.
		MDC_DIM_PER_MIN	{count}/min	264672		
		MDC_DIM_PULS_PER_MIN	{pulse}/min	264896		

Annex A Physiological Monitoring Annex

A.1 Introduction and Purpose

The Physiological Monitoring Value Set defined in this Annex constrains the Harmonized Rosetta [NIST-hRTM] by clarifying and restricting allowable observational identifiers ("terms") within the physiological monitoring domain. Physiological monitors are not expected to produce all these identifiers and may produce additional identifiers outside the scope of this profile.

C4MI has identified twelve categories of observational identifiers related to physiological monitoring, comprising 206 of the 910 observational identifiers currently in hRTM. Of those 206 identifiers, 63 are representative of most physiological monitoring devices' capabilities and are on the critical path for ICU care and intraoperative monitoring and perioperative care. Accordingly, C4MI has thoroughly reviewed these identifiers and provided additional clarity and disambiguation where needed.

C4MI has also discovered 8 observational identifiers in hRTM to be redundant, ambiguous, or otherwise incorrect. C4MI intends to propose these terms be deprecated in hRTM, rendering them inappropriate for a DOR to send.

These 63 core terms and the 8 recommended for deprecation define C4MI's 'Physiological Monitoring Value Set'. Not all 206 hRTM physiological monitoring identifiers have been duplicated within this annex, but all are freely accessible through Rosetta Terminology Mapping tables hosted on the NIST website. Specifically, the hRTM table may be accessed at [NIST-hRTM]. Section A.5 lists those observational identifiers determined to be critical path and those recommended for deprecation organized in the following columns: IEEE/C4MI Common term, C4MI Description/Disambiguation, Category, REFID, CF_CODE10, and C4MI Status The IEEE/C4MI Common Term column is populated from hRTM. Edits are made to align with an implied taxonomy and blank fields within the common term column were populated in the same way. REFID and CF_CODE10 columns were taken verbatim from hRTM. Please see hRTM for additional information not included in this annex.

A.2 Terms and Definitions

Table 6. Sampling Methodology

Sampling Methodology	Description
Invasive	Clinical observation obtained directly by an invasive methodology such as an intravascular catheter, connected to a transducer. (i.e. invasive blood pressure)
Non-Invasive	Clinical observation through the use of external devices such as a conventual BP cuff.

Sampling Methodology	Description
Pulse Oximetry	Noninvasive method of measuring oxygen saturation through variation in absorption spectrum of hemoglobin in pulsating blood vessels. Output is arterial Oxygen saturation (SaO2) and Pulse Rate.
Thermodilution	A reliable bedside method for measuring cardiac output by means of a balloon tipped pulmonary artery catheter with a distal thermistor (Swan-Ganz-1972). Measurements of flow are obtained by injecting saline solution of known temperature and volume into the right atrium from a proximal catheter and the temperature is measured as it flows across the thermistor. A computer acquires the thermodilution profile and calculates cardiac output. L/min
Impedance Plethysmography	Noninvasive measure of respiratory rate takes advantage of 2 to 4 ECG electrodes in place for cardiac monitoring to measure the changes in impedance as a function of changes in the cross-section of the thoracic and abdominal cavity generated by movement during respiration.
Measures of Core Temperature	Core temperature (core body temperature) is the operating temperature of the body, specifically in deep structures of the body in comparison to temperatures of peripheral tissues. Measurement is accomplished by means of a thermistor embedded within one of several possible devices but with temperature measurement typically secondary to the primary function of the device. Examples include pulmonary artery catheter, Foley catheter, endotracheal tube etc. Considered the gold standard in accuracy and stability a normal core temperature is 37 degrees C.

Table 7. ECG Morphology

ECG Morphology	Description
QRS complex	A portion of the ECG wave form that represents ventricular depolarization. The largest wave of the typical ECG tracing associated with mechanical contraction of the ventricles.
ST segment	A portion of the ECG wave form that occurs between the QRS and the T wave (repolarization) that represents a brief plateau that should be aligned with the PR segment of the ECG. Eleveation or depression of the ST segment can represent acute ischemia measured in mm or mV. (typically scaled 1mV = 1mm)

ECG Morphology	Description
PR segment	A portion of the ECG wave form immediately following the P wave (atrial depolarization) and preceding the QRS complex aligned with the baseline of the tracing. The PR interval represents the ventricular filling period of the cardiac cycle.
Premature Ventricular Contractions	Also known as a premature ventricular complex, ventricular premature contraction (or complex or complexes) (VPC), ventricular premature beat (VPB), or ventricular extrasystole (VES). A premature depolarization of the heart that originates from the ventricles rather than sinoatrial node, the intrinsic pacemaker of the heart. PVCs are of little consequence as occasional isolated beats, but they may be a harbinger of underlying myocardial disease or ischemia. The frequency of PVCs over time is of interest to clinicians especially a run of several PVCs in sequence also known as Ventricular tachycardia. Sustained runs of Ventricular Tachycardia can deteriorate to Ventricular Fibrillation, precursor to sudden death.

Table 8. Measures of Pressure

Measures of Pressure	Description
Arterial Blood Pressure	Blood pressure generated by the left ventricular output and arterial vascular tone. Measured directly by an intraarterial catheter (invasive) or indirectly by a blood pressure cuff (noninvasive).
Systolic Blood Pressure	Peak pressure generated during the cardiac cycle representing the end point of ventricular contraction.
Diastolic Blood Pressure	Nadir pressure generated during the cardiac cycle representing the end point of ventricular relaxation.
Central Venous Pressure	Invasive pressure obtained from an intravascular catheter placed in the large central veins of the chest. (SVC and IVC). The pressure is measured directly through a pressure transducer (mm Hg)
Pulmonary Arterial Pressure	Blood pressure generated by right ventricular output and the pulmonary arterial vascular bed. The pressure is measured through the distal port of a multi-lumen pulmonary artery catheter.

Measures of Pressure	Description
Right Atrial Pressure	Blood pressure within the right atrium. Mean is equivalent to the central venous pressure. Measured through the proximal port of a multi-lumen pulmonary artery catheter.
Pulmonary Capillary Wedge Pressure Pulmonary Occlusion Pressure	Pressure of the pulmonary capillary bed reflecting the left ventricular end diastolic pressure. The pressure is measured from the distal port of a pulmonary artery catheter positioned in a branch of the pulmonary vascular tree isolating the port from the pulmonary artery pressure. A PCWP provides assessment of total effective fluid volume and indirectly left LV output.

Table 9. Derived Hemodynamics

Derived Hemodynamics	Description	Calculation & Units
Mean Blood Pressure	A time-weighted average of blood pressure values calculated from systolic and diastolic BP values (the cardiac cycle spends 2/3 of the time in diastole). Important as a representation of the perfusion pressure of tissues and organs.	$MAP = \frac{2(Diastolic\ BP) + Systolic\ BP}{3}$ $Units: MAP = mmHg$
Cardiac Output	The volume of blood pumped by the heart per unit of time (liters/minute) as a function of heart rate, contractility, preload and afterload (BP and systemic vascular resistance). Measurement can be made by multiple methods, but the gold standard is by thermodilution with a pulmonary artery catheter and is the method under test.	The differential equation will not be duplicated but the cardiac output is inversely proportional to the mean blood-temperature depression and the duration of transit of cooled blood from the infusion site in right atrium to the thermistor located in the terminal end of the catheter positioned in a pulmonary artery. i.e. the measure is the area under the temperature-time curve. $Units: CO = L/min$

Derived Hemodynamics	Description	Calculation & Units
Stroke Volume	The volume of blood pumped by the heart in a single ventricular contraction or heartbeat.	$SV = \frac{CO}{HR}$ $Units: SV = \frac{mL}{beat}$
Systemic Vascular Resistance	Also known as Total Peripheral Resistance (TPR). Is the resistance to blood flow offered by all of the systemic vasculature, excluding the pulmonary vasculature. Primarily determined by changes in blood vessel diameter, it is also influenced by blood viscosity.	$SVR = \frac{(MAP - CVP)\ X\ 80}{CO}$ $Units: SVR = \frac{dyne.sec}{cm^5}$
Pulmonary Vascular Resistance	The resistance to blood flow offered by the pulmonary vasculature. Influenced not only by pulmonary vasoconstriction but by chronic lung disease, atelectasis, hypoxemia and acidosis.	$PVR = \frac{(MPAP - PCWP)\ X\ 80}{CO}$ $Units: PVR = \frac{dyne.sec}{cm^5}$
Body Surface Area	Calculated surface area of a human body for purposes of normalization relative to body size. *(For many clinical purposes BSA is a better indicator of metabolic mass than body weight because it is less affected by abnormal adipose mass. There are 25 different methods of calculation for BSA.)* A device may use any BSA calculation supported by peer review literature for the derivation under test. Here, the DuBois equation is included as an example.	$BSA = 0.007184\ (W^{0.425}\ X\ H^{0.725})$ $Units\ BSA = m^2$ $Wt = Kg$ $Ht = cm$
Cardiac Index	Cardiac Output normalized to an individual's size by body surface area.	$CI = \frac{CO}{BSA}$ $Units: CI = \frac{L/min}{m^2}$

Derived Hemodynamics	Description	Calculation & Units
Stroke Volume Index	Stroke Volume normalized to an individual's size by body surface area.	$SVI = \frac{CO}{HR\ X\ BSA}$ $Units: SVI = \frac{mL/beat}{m^2}$
Systemic and Pulmonary Vascular Resistance Index	Vascular resistance normalized to an individual's size by body surface area.	$SVRI = \frac{(MAP\ -CVP)\ X\ 80}{CI}$ $Units: SVRI = \frac{dyne.sec.m^2}{cm^5}$ $PVRI = \frac{(MAP\ -PCWP)\ X\ 80}{CI}$ $Units: PVRI = \frac{dyne.sec.m^2}{cm^5}$

A.2.1 ECG Leads

Limb Leads:

The limb leads are recorded by shifting the polarity of the 4 limb leads between 3 reference points classically presented as an inverted isosceles triangle (Einthoven's triangle - show as a green triangle in Figure 2). The arm leads represent the triangles base. The leg leads are combined to represent the vertex of the triangle. The limb leads created 6 unique signals from 3 bipolar and 3 unipolar leads. The bipolar leads, designated as I, II and III; and the unipolar or augmented leads as aVR, aVL and aVF (Blue). These 6 leads together divide the sagittal plane of the chest (and heart) into defined electrical views represented as vectors extending through or from the heart positioned in the center of the triangle. The depolarization wave is measured from the perspective of the positive electrode designated with a (+) below.

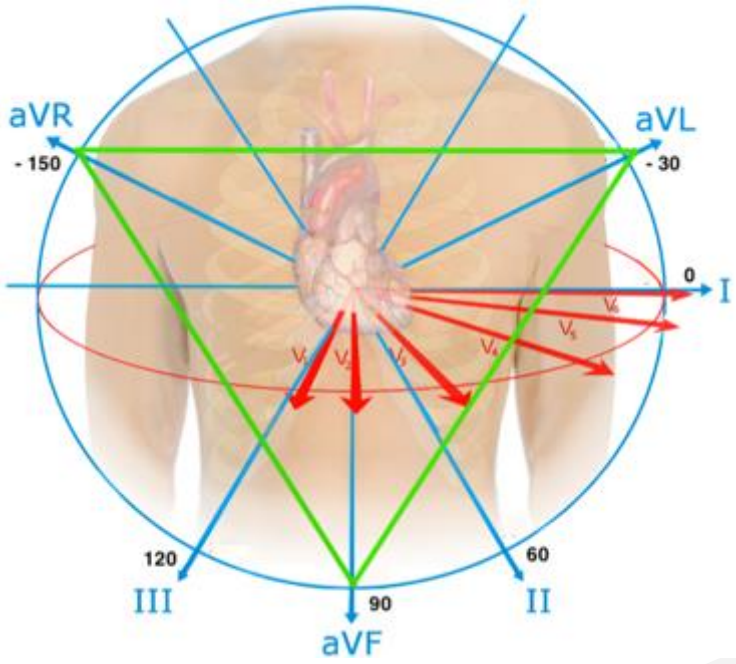
1. Lead I measures the potential between right arm and the left arm (+). Lead I creates the base of the triangle = 0 degrees
2. Lead II measures the potential between the right arm and the legs (+). Lead II is the right leg of the triangle = 60 degrees
3. Lead III measures the potential between the left arm and the legs (+). Lead III is the left leg of the triangle = 120 degrees
4. Lead aVR measures the potential between lead III and the **R**ight arm (+). The left leg of triangle and right arm = -150 degrees

5. Lead aVL measures the potential between lead II and **L**eft arm (+). The right leg of the triangle and left arm = - 30 degrees

6. Lead aVF measures the potential between lead I and Feet (+), The base of the triangle and the feet = 90 degrees

Precordial Leads:

The precordial leads V1 – V6 similarly define depolarization from several perspectives but in the transverse plane of the heart (Red). These six positions extend from the immediate right border of the sternum circumferentially to the mid axillary line of the left chest grounded by the limb leads. They measure the primary vector of depolarization anterolaterally in progression from V1 – V6. Given the proximity to the heart the precordial leads produce the highest deflections in voltage and repolarization.



Original image by [NPatchett]. Modified by C4MI and presented under the Creative Commons License [CC BY-SA 4.0].

Figure 2. Standard Spatial Orientation of a 12 Lead ECG

A.3 Abbreviations and Acronyms

Abbreviations / Acronyms	Description
AP	Arterial Pressure
BP	Blood Pressure
BSA	Body Surface Area

Abbreviations / Acronyms	Description
CI	Cardiac Index
CO	Cardiac Output
CSF	Cerebrospinal Fluid
CV	Cardiovascular
CVP	Central Venous Pressure
DBP	Diastolic Blood Pressure
HR	Heart Rate
IBP	Invasive Blood Pressure
ICP	Intracranial Pressure
IVC	Inferior Vena Cava
LVEDP	Left Ventricular End Diastolic Pressure
LVP	Left Ventricular Pressure
MAP	Mean Arterial Pressure
MPAP	Mean Pulmonary Arterial Pressure
NIBP	Non Invasive Blood Pressure
NOS	Not Otherwise Specified
PAP	Pulmonary Artery Pressure
PCWP	Pulmonary Capillary Wedge Pressure
PVR	Pulmonary Vascular Resistance
PVRI	Pulmonary Vascular Resistance Index
RAP	Right Atrial Pressure
SBP	Systolic Blood Pressure

Abbreviations / Acronyms	Description
SV	Stroke Volume
SVC	Superior Vena Cava
SVR	Systemic Vascular Resistance
SVRI	Systemic Vascular Resistance Index
VT	Ventricular Tachycardia

A.4 Physiological Monitoring Observational Identifier Categories

C4MI Category	Term Count
Blood pressure - method specific	22
Pulse and HR - method specific	3
Oxygen saturation	1
Respiratory rate monitoring	1
Central CV pressures	6
Hemodynamic	6
Vascular resistance	4
ECG - Rate and rhythm	4
ECG - ST Ischemia	12
Intracranial pressure (ICP)	2
Body Temp: method specific	9
Urine output	1
Total	**71**

A.5 hRTM Physiological Monitoring Value Set

IEEE/C4MI Common Term	C4MI Description/ Disambiguation	Category	REFID	CF_ CODE10	C4MI Status
Noninvasive arterial pressure systolic discontinuous	Noninvasive systemic arterial blood pressure - systolic	Blood pressure - method specific	MDC_PRESS_BLD_NONINV_SYS	150021	Preferred Term
Noninvasive arterial pressure diastolic discontinuous	Noninvasive systemic arterial blood pressure - diastolic	Blood pressure - method specific	MDC_PRESS_BLD_NONINV_DIA	150022	Preferred Term
Noninvasive arterial pressure mean discontinuous	Noninvasive systemic arterial blood pressure - mean	Blood pressure - method specific	MDC_PRESS_BLD_NONINV_MEAN	150023	Preferred Term
Noninvasive arterial pressure systolic - continuous	Noninvasive continuous systemic arterial blood pressure - systolic	Blood pressure - method specific	MDC_PRESS_BLD_NONINV_SYS_CTS	150025	Preferred Term
Noninvasive arterial pressure diastolic - continuous	Noninvasive continuous systemic arterial blood pressure - diastolic	Blood pressure - method specific	MDC_PRESS_BLD_NONINV_DIA_CTS	150026	Preferred Term
Noninvasive arterial pressure mean - continuous	Noninvasive continuous systemic arterial blood pressure - mean	Blood pressure - method specific	MDC_PRESS_BLD_NONINV_MEAN_CTS	150027	Preferred Term

IEEE/C4MI Common Term	C4MI Description/ Disambiguation	Category	REFID	CF_ CODE10	C4MI Status
Noninvasive arterial cuff pressure discontinuous	Sphygmomanometer cuff pressure during the measurement of systemic arterial blood pressure	Blood pressure - method specific	MDC_PRESS_CUFF Recommended for Deprecation for blood pressure measurement. Permitted to report the "real-time" NIBP cuff inflation pressure.	150300	Recommended for Deprecation
Noninvasive arterial cuff pressure systolic discontinuous	Sphygmomanometer cuff pressure during the measurement of systemic arterial systolic blood pressure	Blood pressure - method specific	MDC_PRESS_CUFF_SYS Recommended for Deprecation	150301	Recommended for Deprecation
Noninvasive arterial cuff pressure diastolic discontinuous	Sphygmomanometer cuff pressure during the measurement of systemic arterial diastolic blood pressure	Blood pressure - method specific	MDC_PRESS_CUFF_DIA Recommended for Deprecation	150302	Recommended for Deprecation
Noninvasive arterial cuff pressure mean discontinuous	Sphygmomanometer cuff pressure during the measurement of systemic arterial mean blood pressure	Blood pressure - method specific	MDC_PRESS_CUFF_MEAN Recommended for Deprecation	150303	Recommended for Deprecation
Invasive arterial pressure waveform 1^0	Invasive systemic arterial blood pressure primary site (1^0) - waveform	Blood pressure - method specific	MDC_PRESS_BLD_ART_ABP	150036	Preferred Term

IEEE/C4MI Common Term	C4MI Description/ Disambiguation	Category	REFID	CF_ CODE10	C4MI Status
Invasive arterial pressure systolic 1^0	Invasive systemic arterial blood pressure primary site (1^0) - systolic	Blood pressure - method specific	MDC_PRESS_BLD_ART_ABP_SYS	150037	Preferred Term
Invasive arterial pressure diastolic 1^0	Invasive systemic arterial blood pressure primary site (1^0) - diastolic	Blood pressure - method specific	MDC_PRESS_BLD_ART_ABP_DIA	150038	Preferred Term
Invasive arterial pressure mean 1^0	Invasive systemic arterial blood pressure primary site (1^0) - mean	Blood pressure - method specific	MDC_PRESS_BLD_ART_ABP_MEAN	150039	Preferred Term
Invasive arterial pressure waveform 2^0	Invasive systemic arterial blood pressure secondary site (2^0) - waveform	Blood pressure - method specific	MDC_PRESS_BLD_ART	150032	Preferred Term
Invasive arterial pressure systolic 2^0	Invasive systemic arterial blood pressure secondary site (2^0) - systolic	Blood pressure - method specific	MDC_PRESS_BLD_ART_SYS	150033	Preferred Term
Invasive arterial pressure diastolic 2^0	Invasive systemic arterial blood pressure secondary site (2^0) - diastolic	Blood pressure - method specific	MDC_PRESS_BLD_ART_DIA	150034	Preferred Term
Invasive arterial pressure mean 2^0	Invasive systemic arterial blood pressure secondary site (2^0) - mean	Blood pressure - method specific	MDC_PRESS_BLD_ART_MEAN	150035	Preferred Term

IEEE/C4MI Common Term	C4MI Description/ Disambiguation	Category	REFID	CF_ CODE10	C4MI Status
Blood Pressure - NOS	Blood pressure without specification relative to arterial, venous, pulmonary or intracardiac, nor method of acquisition	Blood pressure - method specific	MDC_PRESS_BLD Recommended for Deprecation	150016	Recommended for Deprecation
Blood Pressure Systolic - NOS	Systolic blood pressure without specification relative to arterial, pulmonary or intracardiac, nor method of acquisition	Blood pressure - method specific	MDC_PRESS_BLD_SYS Recommended for Deprecation	150017	Recommended for Deprecation
Blood Pressure Diastolic - NOS	Diastolic blood pressure without specification relative to arterial, pulmonary or intracardiac, nor method of acquisition	Blood pressure - method specific	MDC_PRESS_BLD_DIA Recommended for Deprecation	150018	Recommended for Deprecation
Blood Pressure Mean - NOS	Mean blood pressure without specification relative to arterial, venous, pulmonary or intracardiac, nor method of acquisition	Blood pressure - method specific	MDC_PRESS_BLD_MEAN Recommended for Deprecation	150019	Recommended for Deprecation
Noninvasive arterial pulse - BP monitor	Noninvasive systemic arterial pulse obtained from automated BP monitor	Pulse and HR - method specific	MDC_PULS_RATE_NON_INV	149546	Preferred Term

IEEE/C4MI Common Term	C4MI Description/ Disambiguation	Category	REFID	CF_ CODE10	C4MI Status
Noninvasive arterial pulse - pulse oximetry	Noninvasive systemic arterial pulse obtained from pulse oximetry	Pulse and HR - method specific	MDC_PULS_OXIM_PULS_RATE	149530	Preferred Term
Invasive arterial pulse	Invasive systemic arterial pulse obtained from intra-arterial catheter	Pulse and HR - method specific	MDC_BLD_PULS_RATE_INV	149522	Preferred Term
Oxygen saturation SpO2 - Pulse oximetry	Peripheral oxygen saturation by pulse oximetry	Oxygen saturation	MDC_PULS_OXIM_SAT_O2	150456	Preferred Term
Respiratory rate by impedance	Respiratory rate by transthoracic impedance	Respiratory rate monitoring	MDC_TTHOR_RESP_RATE	151578	Preferred Term
Central venous pressure	Central venous pressure from venae cava	Central CV pressures	MDC_PRESS_BLD_VEN_CENT Equivalent Alternate to MDC_PRESS_BLD_VEN_CENT_MEAN	150084	Preferred Term
Central venous pressure - mean	Central venous pressure from venae cava	Central CV pressures	MDC_PRESS_BLD_VEN_CENT_MEAN Equivalent Alternate to MDC_PRESS_BLD_VEN_CENT	150087	Preferred Term
Pulmonary artery pressure systolic	Pulmonary artery pressure systolic	Central CV pressures	MDC_PRESS_BLD_ART_PULM_SYS	150045	Preferred Term

IEEE/C4MI Common Term	C4MI Description/ Disambiguation	Category	REFID	CF_ CODE10	C4MI Status
Pulmonary artery pressure diastolic	Pulmonary artery pressure diastolic	Central CV pressures	MDC_PRESS_BLD_ART_PULM_DIA	150046	Preferred Term
Pulmonary artery pressure mean	Pulmonary artery pressure mean	Central CV pressures	MDC_PRESS_BLD_ART_PULM_MEAN	150047	Preferred Term
Pulmonary artery wedge pressure	Pulmonary artery wedge pressure (surrogate for LVEDP, preload)	Central CV pressures	MDC_PRESS_BLD_ART_PULM_WEDGE MDC_PRESS_BLD_ART_PULM_OCCL True Synonym	150052	Preferred Term
Cardiac output	Cardiac output measured intermittently	Hemodynamics	MDC_OUTPUT_CARD Equivalent Alternate to MDC_OUTPUT_CARD_NONCTS	150276	Preferred Term
Discontinuous cardiac output	Cardiac output measured intermittently	Hemodynamics	MDC_OUTPUT_CARD_NONCTS Equivalent Alternate to MDC_OUTPUT_CARD	150496	Preferred Term
Continuous cardiac output	Cardiac output measured continuously	Hemodynamics	MDC_OUTPUT_CARD_CTS	150492	Preferred Term
Cardiac index	Cardiac output normalized by body surface area	Hemodynamics	MDC_OUTPUT_CARD_INDEX	149772	Preferred Term

IEEE/C4MI Common Term	C4MI Description/ Disambiguation	Category	REFID	CF_ CODE10	C4MI Status
Stroke volume	Volume of blood ejected per beat	Hemodynamics	MDC_VOL_BLD_STROKE	150404	Preferred Term
Stroke volume Index	Volume ejected per beat normalized by body service area	Hemodynamics	MDC_VOL_BLD_STROKE_INDEX	150636	Preferred Term
Pulmonary vascular resistance	Pulmonary arterial vascular resistance (MPAP - PCWP / CO)	Vascular resistance	MDC_RES_VASC_PULM	150308	Preferred Term
Pulmonary vascular resistance Index	Pulmonary arterial vascular resistance normalized by cardiac index (MPAP - PCWP / CI)	Vascular resistance	MDC_RES_VASC_PULM_INDEX	152852	Preferred Term
Systemic vascular resistance	Systemic arterial vascular resistance (MAP - CVP / CO)	Vascular resistance	MDC_RES_VASC_SYS	150312	Preferred Term
Systemic vascular resistance index	Systemic vascular resistance normalized by cardiac index (MAP - CVP / CI)	Vascular resistance	MDC_RES_VASC_SYS_INDEX	149760	Preferred Term
Heart rate - ECG	Heart rate obtained from ECG QRS complex	ECG - Rate and rhythm	MDC_ECG_HEART_RATE MDC_ECG_CARD_BEAT_RATE True Synonym	147842	Preferred Term

IEEE/C4MI Common Term	C4MI Description/ Disambiguation	Category	REFID	CF_ CODE10	C4MI Status
Heart rate - paced rhythm	Heart rate comprised of pacemaker generated QRS complexes	ECG - Rate and rhythm	MDC_ECG_PACED_BEAT_RATE	147626	Preferred Term
Premature ventricular contraction rate	Rate of premature ventricular contractions	ECG - Rate and rhythm	MDC_ECG_V_P_C_RATE	148066	Preferred Term
Premature ventricular contraction count	Count of premature ventricular contractions (useful in describing a nonsustained run or salvo, i.e. short run of VT)	ECG - Rate and rhythm	MDC_ECG_V_P_C_CNT MDC_ECG_VPC_COUNT True Synonym	148065	Preferred Term
ECG ST Depression I	Myocardial ischemia as ST Depression Lead I	ECG - ST Ischemia	MDC_ECG_AMPL_ST_I	131841	Preferred Term
ECG ST Depression II	Myocardial ischemia as ST Depression Lead II	ECG - ST Ischemia	MDC_ECG_AMPL_ST_II	131842	Preferred Term
ECG ST Depression III	Myocardial ischemia as ST Depression Lead III	ECG - ST Ischemia	MDC_ECG_AMPL_ST_III	131901	Preferred Term
ECG ST Depression aVR	Myocardial ischemia as ST Depression Lead aVR	ECG - ST Ischemia	MDC_ECG_AMPL_ST_AVR	131902	Preferred Term

IEEE/C4MI Common Term	C4MI Description/ Disambiguation	Category	REFID	CF_ CODE10	C4MI Status
ECG ST Depression aVL	Myocardial ischemia as ST Depression Lead aVL	ECG - ST Ischemia	MDC_ECG_AMPL_ST_AVL	131903	Preferred Term
ECG ST Depression aVF	Myocardial ischemia as ST Depression Lead aVF	ECG - ST Ischemia	MDC_ECG_AMPL_ST_AVF	131904	Preferred Term
ECG ST Depression V1	Myocardial ischemia as ST Depression Lead V1	ECG - ST Ischemia	MDC_ECG_AMPL_ST_V1	131843	Preferred Term
ECG ST Depression V2	Myocardial ischemia as ST Depression Lead V2	ECG - ST Ischemia	MDC_ECG_AMPL_ST_V2	131844	Preferred Term
ECG ST Depression V3	Myocardial ischemia as ST Depression Lead V3	ECG - ST Ischemia	MDC_ECG_AMPL_ST_V3	131845	Preferred Term
ECG ST Depression V4	Myocardial ischemia as ST Depression Lead V4	ECG - ST Ischemia	MDC_ECG_AMPL_ST_V4	131846	Preferred Term
ECG ST Depression V5	Myocardial ischemia as ST Depression Lead V5	ECG - ST Ischemia	MDC_ECG_AMPL_ST_V5	131847	Preferred Term
ECG ST Depression V6	Myocardial ischemia as ST Depression Lead V6	ECG - ST Ischemia	MDC_ECG_AMPL_ST_V6	131848	Preferred Term

IEEE/C4MI Common Term	C4MI Description/ Disambiguation	Category	REFID	CF_ CODE10	C4MI Status
Mean intracranial pressure (ICP)	Direct pressure of CSF measured by intracranial catheter	Intracranial pressure (ICP)	MDC_PRESS_INTRA_CRAN_MEAN	153611	Preferred Term
Cerebral perfusion pressure	Difference between mean arterial pressure and ICP	Intracranial pressure (ICP)	MDC_PRESS_CEREB_PERF	153604	Preferred Term
Body temperature	Body temp NOS	Body Temp: method specific	MDC_TEMP	150344	Preferred Term
Body temperature - Core	Body temp - Core	Body Temp: method specific	MDC_TEMP_CORE	150368	Preferred Term
Rectal temperature	Body temp - Rectal	Body Temp: method specific	MDC_TEMP_RECT	188420	Preferred Term
Tympanic membrane temperature	Body temp - TM	Body Temp: method specific	MDC_TEMP_TYMP	150392	Preferred Term
Bladder temperature via Foley	Body temp - Foley (Bladder)	Body Temp: method specific	MDC_TEMP_FOLEY	150348	Preferred Term
Airway temperature	Body temp - Airway (ET-tube)	Body Temp: method specific	MDC_TEMP_AWAY	150356	Preferred Term

IEEE/C4MI Common Term	C4MI Description/ Disambiguation	Category	REFID	CF_ CODE10	C4MI Status
Esophageal temperature	Body temp - Esophageal	Body Temp: method specific	MDC_TEMP_ESOPH	150372	Preferred Term
Nasopharyngeal temperature	Body temp - Nasopharyngeal	Body Temp: method specific	MDC_TEMP_NASOPH	150380	Preferred Term
Skin temperature - infant incubator	Body temp - Incubator (infant)	Body Temp: method specific	MDC_TEMP_SKIN	150388	Preferred Term
Urine volume	Volume of urine collected for unspecified duration	Urine output	MDC_VOL_URINE_COL	157744	Preferred Term

Annex B Provisioning

B.1 Introduction

IP network connectivity must be established by DORs before communication with a DOC can be established. This section establishes DOR support for a set of tools, enabling HDOs to on-board devices to their network by providing addresses, home domain, and resources for domain resolution and network time. This section relies on an existing connection to the HDO access network (e.g. Ethernet, WiFi).

B.2 IP Network Connectivity

Once a DOR has connected to an access network, it must obtain an IP address for care related communications on an IP network. A DOR is also responsible for obtaining specific, additional information during initialization: NTP server address, domain name server address, and the domain name. These are all obtained via DHCP.

B.2.1 DHCPv4 Requirement

A DOR that communicates via an IPv4 network and has responsibility to obtain its IP address SHALL use DHCPv4 [IETF-RFC2131].

B.2.2 DHCPv6 Requirement

A DOR that communicates via an IPv6 network and has responsibility to obtain its IP address SHALL use DHCPv6 [IETF-RFC3315].

B.2.3 IPv6-v4 Fallback Requirement

A DOR that supports both DHCPv4 and DHCPv6 SHALL select source and destination addresses per [IETF-RFC6724].

B.2.4 DHCPv4 Request Requirement

For DHCPv4, the DOR SHALL request DHCP options #42 (NTP server), #6 (DNS Server), and #15 (domain name) [IETF-RFC2132].

B.2.5 DHCPv6 Request Requirement

For DHCPv6, the DOR SHALL request DHCP options specified in [IETF-RFC5908] (NTP), [IETF-RFC3646] (DNS, domain search list), and [IETF-RFC4704] (FQDN).

B.2.6 Missing DHCP Options Requirement

In the presence of multiple DHCP responses, the DOR selects one, as specified in [IETF-RFC2131] or [IETF-RFC3315], that provides the required options. When one or more of the options are not provided, the DOR SHALL treat it as a failure in the DHCP process.

Annex C Secure Transport

C.1 Introduction

This section outlines requirements for DORs securing connections to DOCs prior to sending data as described in this specification.

Secure connections between Connected Components require common encryption methods and a trust framework. This section outlines the methods for leveraging identity and authenticating devices using a profile based on TLS version 1.2. This section does not establish a trust framework, shared between DORs and DOCs. A trust framework, in the form of a public key infrastructure (PKI), can be developed by device manufacturers, service providers, or health delivery organizations to fit their application. Any organization seeking to implement a PKI for use with the profile defined in this section should consider the guidance presented in C4MI certificate policy documents [CMI-SP-F-CP] and IETF best practices documents [IETF-BCP195].

C.2 Cryptographic Requirements

C.2.1 TLS Requirement

A DOR SHALL establish a secure TLS [IETF-RFC5246] connection to be used for exchanging messages. A DOR SHALL initiate the TLS connection.

C.2.2 TLS Version Requirement

DORs SHALL support TLS version 1.2 and MAY also support higher versions. DORs SHALL NOT use a TLS protocol version lower than 1.2.

C.2.3 RSA ECC Support Requirement

DORs SHALL support one of RSA and ECC cryptography schemes for certificate validation procedures. To promote interoperability across systems, DORs MAY support both cryptography schemes.

C.2.4 Algorithm Support Requirement

DORs SHALL support one of ECDHE and DHE algorithms for secure key exchange. DORs SHALL support the SHA-2 hashing algorithm family (e.g., SHA-256, SHA-384, and SHA-512) [FIPS-180-4] and MAY support other hashing algorithms with better or similar security. DORs SHALL support AES with key sizes of 128 bits. DORs SHOULD support AES with key size 256 bits.

C.2.5 ECC Curve Support Requirement

DORs that support ECC cryptography [IETF-RFC8422] SHALL support NIST curves [FIPS-186-4] and MAY support additional curves with similar or stronger security.

C.2.6 ECC Cipher Requirement

DORs that support ECC cryptography SHALL support at least one of the following TLS cipher suites:

Table 10. ECC Cipher Suites

Cipher Suite	Reference
TLS_ECDHE_ECDSA_WITH_AES_128_CBC_SHA256	[IETF-RFC5289]
TLS_ECDHE_ECDSA_WITH_AES_256_CBC_SHA	[IETF-RFC8422]
TLS_ECDHE_ECDSA_WITH_AES_256_GCM_SHA384	[IETF-RFC5289]

If a DOR supports more than one cipher from Table 10, it SHALL present them with the priority shown in the above list.

C.2.7 RSA Key Size Requirement

DORs that support RSA cryptography SHALL support RSA keys up to 4096 bits for certificate validation and keys up to 2048 bits for signatures.

C.2.8 RSA Cipher Requirement

DORs that support RSA cryptography SHALL support at least one the following TLS cipher suites:

Table 11. RSA Cipher Suites

Cipher Suite	Reference
TLS_DHE_RSA_WITH_AES_128_CBC_SHA256	[IETF-RFC5246]
TLS_DHE_RSA_WITH_AES_256_CBC_SHA256	[IETF-RFC5246]
TLS_DHE_RSA_WITH_AES_256_GCM_SHA384	[IETF-RFC5288]

If a DOR supports more than one cipher from Table 11, it SHALL present them with the priority shown in the above list.

C.2.9 Optional Cipher Requirement

A DOR MAY support TLS_ECDHE_RSA_WITH_AES_256_GCM_SHA384 [IETF-RFC5289] which uses both ECC and RSA public key cryptography. If supported, a DOR SHALL add the cipher to the top of the list of ciphers presented in the Client Hello message.

C.3 Authentication Requirements

C.3.1 Issuing Certificate Requirement

During TLS authentication messaging, a DOR SHALL include the issuing CA certificate with its own certificate in the TLS Certificate message.

C.3.2 Basic Path Validation Requirement

A DOR SHALL validate certificates that it receives using Basic Path Validation procedures defined in the X.509 PKI certificate profile [IETF-RFC5280]. If a DOR cannot validate the received certificates, it SHALL reject authentication, log an error, and close the connection.

C.3.3 Host Validation Requirement

During Basic Path Validation procedures, a DOR SHALL verify that the host portion of the destination URL matches a domain name in the Subject Alternative Name extension of the received certificate. If a DOR cannot validate the source of the received certificates, it SHALL reject authentication.

C.3.4 OCSP Requirement

When performing certificate validation, a DOR SHALL check the revocation status of the received certificate using OCSP [IETF-RFC6960] responses provided via OCSP Stapling during the initial TLS message exchange. A DOR SHALL also verify that the responses are correctly signed and that the certificate of the OCSP signer is properly validated.

C.3.5 Authenticity and Freshness Requirement

OCSP Responses and CRLs SHALL be validated by a DOR for authenticity and freshness before they can be used to check the revocation status of a certificate.

C.3.6 Response for Revoked Certificate Requirement

If a certificate has been revoked or if its revocation status is unknown, a DOR SHALL reject authentication.

C.3.7 Key Storage Requirement

A DOR SHOULD store the certificate private key in a manner that deters unauthorized disclosure and modification.

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