

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

# CMI-SP-CDI-IHE-PCD-SSE-D02-2019-05-31

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# **Document Status Sheet**

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## Key to Document Status Codes

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 generally 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**

A Survey of HIMSS participants identified "plug and play" interoperability and the need to share Patient Care Device (PCD) data as the highest priority when questioned about PCD requirements. The demand for PCD data has increased post EHR deployment with enhanced clinician access, visualization, and utilization. In spite of 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, visualization is enhanced, and data can be correlated and blended into coherent clinical pictures. These are all compelling reasons the Center prioritizes testing and certification of PCD data output.

As a framework The Center references the "Integrating the Healthcare Enterprise" (IHE) Initiative. Over the past 20 years IHE has addressed ten different clinical and operational domains of which PCD is one. Within the PCD domain there are eleven Integration Profiles. This specification addresses the following:

- 1. The Device Enterprise Communication (DEC) addresses the transmission of information from medical devices at the point of care to enterprise applications.
- 2. The Rosetta Terminology Mapping (RTM) reduces effort and error in mapping device data from multiple vendors to the enterprise.

This document leverages the semantic standards described in sections 6, 7 and 8 of the Clinical Data Interoperability-IHE PCD specification. These standards are maintained in the Harmonized RTM (hRTM), a derivative work of the ISO/IEEE 11073 nomenclature. The Rosetta Terminology Mapping Management System (RTMMS) is supported and hosted by NIST with development and curation of new terms, principally by the IEEE 11073 community. The hRTM has been identified by NIST as the source-of-truth to define and co-constrain observation identifiers in PCD message transactions.

Included within the RTM are unique alpha and numeric IDs, units-of measure, enumeration values, measurement sites, common terms and vendor descriptions of terms currently in use by a vendor. In some cases, this specification will further constrain these identifiers by selecting a preference in the case of true (non-synonymous) duplication or disambiguate in the case of co-option.

The standards and profiles of the IHE PCD - DEC are referenced but not duplicated within this specification. As noted above the "Clinical Data Interoperability Specification" describes the general standards and requirements necessary for conforming Device Observation Reporters (DOR) and Device Observation Consumers (DOC).

## **1.2 Requirements**

Throughout this document, the words that are used to define the significance of particular requirements are capitalized. These words are:

"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 the case 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 this item is truly optional. One vendor may choose to include the item because a particular marketplace requires it or because it enhances the product, for example; 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.

[IHE-PCD-TF-1]	IHE Patient Care Device (PCD) Technical Framework, Volume 1, IHE PCD TF- 1, Profiles (Revision 8.0 – Final Text, October 23, 2018)
	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, Transactions (Revision 8.0 – Final Text, October 23, 2018)
	https://www.ihe.net/resources/technical_frameworks/#pcd
[HL7-V2.6]	Health Level Seven International HL7 V2.6
	http://www.hl7.org/implement/standards/product_brief.cfm?product_id=1 45
[HL7-V2.8.2- PRT]	HL7 Messaging Standard Version 2.8.2, Section 7.4.4 PRT – Participation Information Segment
	http://www.hl7.org/implement/standards/product_brief.cfm?product_id=4 03
[IEEE-10101- 2004]	Health informatics – Point-of-care medical device communication – Part 10101: Nomenclature (ISO/IEEE 11073-10101:2004)
	Defines a comprehensive vital signs nomenclature suitable for patient monitors, infusion pumps, anesthesia machines, and ventilators and other devices.
	http://standards.ieee.org/findstds/standard/11073-10101-2004.html

[IEEE-10101a- 2015]	Health informatics – Point-of-care medical device communication – Part 10101: Nomenclature – Amendment 1: Additional Definitions 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.
	http://standards.ieee.org/findstds/standard/11073-10101a-2015.html
[IHE-ITI-TF-1]	IHE IT Infrastructure (ITI) Technical Framework, Volume 1 (ITI TF-1), Integration Profiles (Revision 14.0 – Final Text, July 21, 2017) 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).
	http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol1.pdf
[IHE-ITI-TF-2a]	IHE IT Infrastructure (ITI) Technical Framework, Volume 2a (ITI TF-2a), Integration Transactions Part A – Sections 3.1 – 3.28 (Revision 14.0 – Final Text, July 21, 2017) 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).
	http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol2a.pdf
[IHE-ITI-TF-2b]	IHE IT Infrastructure (ITI) Technical Framework, Volume 2b (ITI TF-2b), Integration Transactions Part B– Sections 3.29 – 3.64 (Revision 14.0 – Final Text, July 21, 2017)
	Defines the 'Patient Identity Management' [ITI-30] transaction to transmit patient demographics information.
	http://www.ihe.net/uploadedFiles/Documents/ITI/IHE_ITI_TF_Vol2b.pdf

[NIST-RTMMS]	NIST Rosetta Terminology Mapping Management System (RTMMS) The RTMMS functions are listed below. An on-line and downloadable Users Guide is available. MyRosetta – Vendor specific terms (registration required) Rosetta – Public vendor and standard terms Units – Units of measure (MDC with mappings to UCUM, dimensionality, unit-groups) Enums – Enumerated values hRTM – Harmonized Rosetta (880+ terms with units, enums, and measurement-site co- constraints) Groups – Term groups (to facilitate development and documentation) IEEE 11073 to LOINC Mapping – Mapping of 600+ IEEE 11073 hRTM to LOINC terms (registration required) X73 – Published IEEE 11073 Nomenclature Standards (registration required) https://rtmms.nist.gov/
[NIST-hRTM]	NIST RTMMS 'Harmonized Rosetta' 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.
	https://rtmms.nist.gov/rtmms/index.htm#!hrosetta
[IETF-RFC4180]	Common Format and MIME Type for Comma-Separated Values (CSV) Files.
	https://tools.ietf.org/html/rfc4180
[CMI-SP-F-ANC]	Access Network Connectivity
	https://medicalinteroperability.org/specifications

## 2.2 Informative References

This specification uses the following informative references:

F /21 /2010	The Conten for Medical Interproperability (CMI)
	https://www.iso.org/standard/44863.html
[IEC-80001- 1:2010]	ISO/IEC 80001-1 Ed.1: Application of risk management for it-networks incorporating medical devices – Part 1: Roles, responsibilities, and activities.
	http://standards.ieee.org/findstds/standard/11073-20101-2004.html
	information model defines the modeling, formatting, and the syntax for encoding and transmission of objects. Other topics, such as the association between 'device' and 'manager', are also specified. [Required elements of this standard have been incorporated in the IHE PCD DEC Technical Framework.]
[IEEE-20101- 2004]	<ul> <li>Health informatics – Point-of-care medical device communication – Part</li> <li>20101: Application Profile – Base Standard (ISO/IEEE 11073-</li> <li>20101:2004)</li> <li>This standard defines a communication model and an information model. The</li> <li>communication model describes the layers 5 to 7 of the OSI 7-layer model and the</li> </ul>
	http://standards.ieee.org/findstds/standard/11073-10201-2004.html
[IEEE-10201- 2004]	Health informatics – Point-of-care medical device communication – Part 10201: Domain Information Model (ISO/IEEE 11073-10201:2004) Defines the objects and their relationships in a Domain Information Model for vital signs data transfer and defines a service model for standardized communication. [Required elements of this standard have been incorporated in the IHE PCD DEC Technical Framework.]
	http://standards.ieee.org/findstds/standard/11073-10102-2012.html
	2012) The ECG lead designators defined by -10102 are used by IHE PCD DEC, ACM, and WCM for enterprise numeric and waveform data exchange. The aECG lead designators have also been adopted by ANSI/HL7 V3 ECG, R1-2004 (R2009); HL7 V3 IG aECG R1 (2005); DICOM Supplement 128 (2008), and EN1064 (EN1064:2005+A1:2007).
[IEEE-10102- 2012]	Health informatics – Point-of-care medical device communication – Part 10102: Nomenclature – Annotated ECG (ISO/IEEE 11073-10102- 2012)
	https://www.ihe.net/resources/technical_frameworks/#pcd
[IHE-PCD-TF-3]	IHE Patient Care Device (PCD) Technical Framework, Volume 3, IHE PCD TF-3, Semantic Content (Revision 8.0 – Final Text, October 23, 2018)

[CMI-DOC-TD]	Terms and Definitions
	https://medicalinteroperability.org/specifications
[IETF-RFC2119]	Key words for use in RFCs to Indicate Requirement Levels https://tools.ietf.org/html/rfc2119
[Oemig/Snelick]	Frank Oemig and Robert Snelick, Healthcare Interoperability Standards Compliance Handbook: Conformance and Testing of Healthcare Data Exchange Standards, Springer International Publishing, 1st ed, 2016.

https://www.springer.com/us/book/9783319448374

#### 2.3 Reference Acquisition

- Center for Medical Interoperability, 8 City Boulevard, Suite 203 | Nashville, TN 37209; Phone +1-615-257-6410; <u>http://medicalinteroperability.org/</u>
- 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, <u>http://www.ietf.org</u>
- 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, <a href="http://standards.ieee.org/findstds/index.html">http://standards.ieee.org/findstds/index.html</a>
- 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, <a href="http://www.hl7.org/">http://www.hl7.org/</a>
- 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, <u>http://www.iso.org</u>

#### 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

The Center for Medical Interoperability (CMI)

5/31/2019

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. <i>Example: 68321^MDC_ATTR_SAMPLE_COUNT^MDC (non-zero code, MDC_ REFID)</i>
'proposed'	Interim terms without numeric codes that have not gone through a formal review process, typically used for initial prototyping. <i>Example: 0^MDCX_ECG_QT_DISPERSION^MDC (zero code, MDCX_ REFID)</i>
'private'	Vendor-defined proprietary terms with permanent 'private' code assignment. These are ignored for testing purposes. Example: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:

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)
СМІ	Center For Medical Interoperability
СТ	Consistent Time (IHE ITI-1)
DOC	Device Observation Consumer (IHE PCD DEC)
DOR	Device Observation Reporter (IHE PCD DEC)
HIMSS	Health Information Management Systems Society
HL7	Health Level Seven International
IEEE	Institute of Electrical and Electronics Engineers
IHE PCD	Integrating the Healthcare Enterprise Patient Care Device
MLLP	Minimum Lower Layer Protocol (HL7)
NIST	National institute of Standards and Technology
NTP	Network Time Protocol (IETF)
РАМ	Patient Administration Management (IHE ITI-30 Patient Identity Feed)
PDQ	Patient Demographics Query (IHE ITI-21)
РКІ	Public Key Infrastructure
PoCD	Point-of-Care Device (alternative, Point-of-Care Diagnostic)
REFID	IEEE 11073 Reference ID (OBX-3.2)
RTMMS	Rosetta Terminology Mapping Management System
TLS	Transport Layer Security
UCUM	Unified Code for Units of Measure. (OBX-6.1)
UOM	Units of Measure (OBX-6.1)

#### **5** Overview

#### 5.1 Architecture

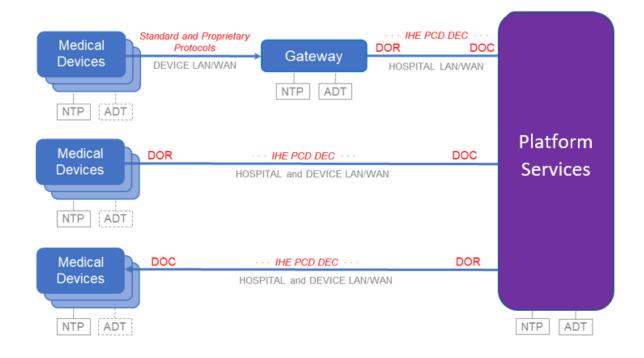
Medical Devices, Gateways, and Platform Services are considered connected components. Once a connected component is granted network access, it communicates with other connected components using IHE PCD HL7 messaging and the MLLP transport protocol. The requirements for network access, device authentication and authorization, and network and messaging security and confidentiality are defined in The Center's Access Network specification [CMI-SP-F-ANC] and are a precondition for the discussion that follows.

Two IHE PCD 'Actors' are defined by the IHE PCD 'Device to Enterprise Communication' (DEC) profile to support the 'Communicate Device Data' (PCD-01) transaction. The first is the 'Device Observation Reporter' (DOR) that sends data such as vital signs and device status information. The second is the 'Device Observation Consumer' (DOC) that receives the data and processes, displays, stores, and forwards the information and aggregates it with data from other devices.

The diagram below shows three possible configurations that can be used individually or concurrently with the Center-defined 'Platform Services'. The first shows proprietary or standardized data from one or more Medical Devices going through a Gateway that translates and/or forwards it to the Platform using the PCD-01 transaction.<sup>1</sup> The second shows a Medical Device sending its data directly to the Platform Services using the PCD-01 transaction. The third configuration illustrates a Medical Device acting as a DOC. In all configurations, the data is sent as unsolicited HL7 V2 'ORU' messages by the DOR and the DOC is required to send an acknowledgment for each message that it receives.<sup>2</sup>

<sup>&</sup>lt;sup>1</sup> Proprietary messaging is not in the scope of this specification.

<sup>&</sup>lt;sup>2</sup> Although connections are bidirectional, the predominant information flow is DOR to DOC, as depicted by the arrowheads



#### Figure 1: Architecture showing IHE PCD HL7 Interfaces

Before a connected component communicates with the Platform using IHE PCD messaging, it first establishes a secure connection using TLS. This includes mutual authentication of device identities using a device certificate, message encryption, and message authentication.

#### 6 Device Observation Reporter Requirements

#### 6.1 Introduction

This section defines the general requirements for Medical Devices, Gateways, and Platforms to establish interoperable communication of Medical Device data using IHE PCD DEC messaging as a DOR Actor, using the HL7 V2.6 message syntax, and IEEE 11073 medical device semantics (aka nomenclature). These requirements are applicable to any observational identifier sent by a DOR.

Annexes to this specification include profiles that constrain the Harmonized Rosetta [NIST-hRTM] by clarifying and restricting observational identifiers by functional domain. For example, the Physiological Monitoring Annex includes observational identifiers for data originating from patient monitoring devices. The Center intends to propose these clarifications and restrictions for inclusion in Harmonized Rosetta [NIST-hRTM].

#### 6.2 Messages

#### 6.2.1 DOR Message IHE PCD TF Requirement

Messages sent by the DOR SHALL comply with [IHE-PCD-TF-1] and [IHE-PCD-TF-2].

#### 6.2.2 Syntax

#### 6.2.2.1 DOR Message Syntax Requirement

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

#### 6.2.2.2 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].

#### 6.2.3 Observations

#### 6.2.3.1 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 a term appropriate for the message's content:

1. 'approved and published' terms from the Harmonized Rosetta [NIST-hRTM] as constrained by profiles defined in this specification

- 2. 'provisional' terms from the Harmonized Rosetta [NIST-hRTM]
- 3. non-deprecated terms from a published IEEE 11073-10101 standard [IEEE-10101-2004] [IEEE-10101a-2015]
  - 4. 'private' terms (see 'DOR Message hRTM Private Terms Requirement')

This requirement may be modified in future iterations of this specification to support the latest term approval status as defined by the IHE PCD community.

#### 6.2.3.2 DOR Message hRTM Proposed Terms Requirement

The primary OBX-3 (.1, .2, .3) identifier in any message sent by the DOR SHALL NOT be a 'proposed' term from the Harmonized Rosetta. (If a 'proposed' term is made 'provisional', that 'provisional' term can be used.)

#### 6.2.3.3 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. The Center reserves the right to revisit certification of any DOR that uses any terms from the Harmonized Rosetta [NIST-hRTM] that are later deprecated.

#### 6.2.3.4 DOR Message Private Terms Requirements

DORs SHOULD NOT send 'private' terms. Future iterations of this specification may fully disallow the use of 'private' terms. 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. If a DOR sends a 'private' term, the DOR vendor SHOULD submit it as a 'proposed' term to [NIST-RTMMS].

# 6.2.3.5 Table 1 - Examples of Permitted IEEE 11073 MDC OBX-3 identifiers using the HL7 V2 CWE datatype

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)

#### 6.2.3.6 DOR Message REFID Synonym Requirement

REFID-synonyms that have the same CF\_CODE10 have been defined for several IEEE 11073 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.

#### 6.2.3.7 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 as an alternative OBX-3 (.4,.5,.6) identifier.

#### 6.2.3.8 DOR Message Semantic Accuracy Requirement

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

### 6.2.4 Co-Constraints

#### 6.2.4.1 DOR Message Co-constraints Requirement

Messages sent by a DOR that use a term from the Harmonized Rosetta [hRTM] as its primary OBX-3 identifier:

- 1. SHALL convey a unit-of-measure from the [NIST-hRTM] UOM\_MDC and/or UOM\_UCUM columns in OBX 6 if and only if any are listed for the [NIST-hRTM] 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 [NIST-hRTM] 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 [NIST-hRTM] 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].

### 6.2.5 Patient Demographics

#### 6.2.5.1 DOR Message Patient Identifier Requirement

The patient identifier sent by the DOR SHALL be obtained using any of the following methods:

1. The IHE ITI Patient Demographics Query (PDQ) profile using the 'Patient Demographics Query' [ITI-21] transaction defined in [IHE-ITI-TF-2a].

2. The Patient Administration Management (PAM) profile using the 'Patient Identity Management' [ITI-30] transaction defined in [IHE-ITI-TF-2b].

3. An authoritative "enterprise-worthy" identifier obtained via a patient bar code or other scanner.

#### 6.3 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.

#### 6.3.1 DOR Disclosure Requirement

DOR vendors SHALL disclose all DOR's reported observations according to the format defined in Appendix I.

#### 6.3.2 DOR "Demo" Mode Requirement

DOR vendors SHALL provide a "send-all" or "demo" mode in which the DOR sends all possible reported observation messages.

#### 6.4 Time

#### 6.4.1 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 of the Consistent Time (CT) profile defined in [IHE-ITI-TF-2a].

#### 6.4.2 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).

#### 6.4.3 DOR Observation Timestamp Requirement

Timestamp values reported in OBR-7, OBR-8 and OBX-14 SHALL indicate the time that the original physiologic observation was made, not the time the message was sent or the data was later cached, archived or sent in response to a query. This specifically applies, but is not limited to, numeric and waveform observations, settings and enumerations, events, alerts and annotations, commands and other procedures, to within the time latency that the device, system or clinician is capable of noting their occurrence.

#### 7 Device Observation Consumer Requirements

This section defines general requirements for Medical Devices, Gateways, and Platforms to establish interoperable communication of Medical Device data using IHE PCD DEC messaging as a DOC Actor.

The IHE PCD DEC Technical Framework currently does not provide detailed guidance regarding what the Device Observation Consumer (DOC) Actor should do after it receives messages sent by the DOR; the DOC Actor could be a message router that buffers and forwards the data elsewhere or the DOC Actor could be a component of a comprehensive electronic medical record system or clinical decision support application. Aside from the minimal requirements defined in this section, a DOC's functional requirements are out of scope of this specification, including a DOC's ability to store, validate, or display data, semantically integrate data in an application, or support retrospective data queries.

# Messages

#### 7.1.1 Acceptance

#### 7.1.1.1 DOC Message Acceptance Requirement.

A DOC SHALL accept any message that could be reported by a DOR as defined in the section above.

The IHE PCD DEC Device Observation Consumer (DOC) Actor accepts PCD-01 messages sent by the Device Observation Reporter (DOR) and sends an MSA 'AA' Accept Acknowledgement response for each valid DOR message received. The DOC assumes ownership of the data, equivalent to an 'Application Acknowledgement'

#### 7.1.1.2 DOC Message Assessment Requirement

The DOC SHALL make an initial assessment regarding the validity of the DOR messages that it receives. If the DOR message is initially considered valid and can be accepted by the DOC, the DOC SHALL send an MSA 'AA' Accept Acknowledgement response; otherwise, the DOC SHALL send an MSA 'AE' Error or 'AR' Reject response. For example, If MSH-1 or MSH-2 do not contain HL7 recommended values, the DOC MAY reject the entire message.

#### 7.1.1.3 DOC Message Ownership Requirement

In all (use) cases, the DOC SHALL assume ownership of the data when it sends the MSA 'AA' Accept Acknowledgement response for each valid DOR message received and the DOR MAY discard the information after receiving the 'AA' Accept Acknowledgement.

#### 7.1.2 Forwarding

#### 7.1.2.1 DOC Message Forwarding Requirement

If a DOC is capable of forwarding messages, it SHALL be capable of forwarding all messages received from a DOR as an unmodified IHE PCD DEC PCD-01 message stream. When forwarding, a DOC MAY update OBR-7, OBR-8, or OBX-14 timestamps to use the local time zone offset.

#### 8 Appendix I: DOR Disclosure Format

This Appendix defines the contents and format of a DOR disclosure. The disclosure uses a format similar to the NIST RTMMS [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 Appendix II.1 for a simple vital signs monitor and Appendix II.2 for an infant incubator or warmer.

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 CVS 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 3.

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.

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.

The phrase "multi-line list" is used throughout Table 3 to refer to a list of items delimited by a carriage return and line feed ('rn').

## 8.1 DOR Disclosure Content Table

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 optional.
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.

### 8.2 Simple Vital Signs Monitor (VSM) (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 4 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 5 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.

#### 8.3 Infant Incubator or Warmer (Informative)

The DOR disclosure in Table 6 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 are.

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.

# 8.3.1 Table: 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_02_CHAN	SpO2 (Channel)	69643					
MDC_PULS_OXIM_SAT_02	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					
	Resp Rate (Channel)	69723					
MDC_DEV_ANALY_RESP_RATE_CHAN							
MDC_RESP_RATE	Resp Rate	151562	MDC_DIM_RESP_PER_MIN	{resp}/min	264928		
. MDC_DEV_PRESS_BLD_NONINV_VMD	NIBP (VMD)	70686					
	Systolic/Diastolic/MAP/Rate	70687		•			
MDC_DEV_PRESS_BLD_NONINV_CHAN							
MDC_PRESS_BLD_NONINV_SYS	Systolic	150021	MDC_DIM_MMHG	mm[Hg]	266016		
			MDC_DIM_KILO_PASCAL	kPa	265987		
MDC_PRESS_BLD_NONINV_DIA	Diastolic	150022	MDC_DIM_MMHG	mm[Hg]	266016		
			MDC_DIM_KILO_PASCAL	kPa	265987		
MDC_PRESS_BLD_NONINV_MEAN	Mean Arterial Pressure	150023	MDC_DIM_MMHG	mm[Hg]	266016		
			MDC_DIM_KILO_PASCAL	kPa	265987		
MDC_PULS_RATE_NON_INV	Pulse Rate	149546	MDC_DIM_BEAT_PER_MIN	{beat}/min	264864		
			MDC_DIM_PER_MIN	{count}/min	264672		
			MDC_DIM_PULS_PER_MIN	{pulse}/min	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	Cel	268192		
			MDC_DIM_FAHR	[degF]	266560		

# 8.3.2 Table - 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_02	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		
	69722				•	•
MDC_DEV_ANALY_RESP_RATE_VMD						
MDC_RESP_RATE	151562	MDC_DIM_RESP_PER_MIN		264928		
	70686					
MDC_DEV_PRESS_BLD_NONINV_VMD						
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		268192		
		MDC_DIM_FAHR		266560		

# 8.3.3 Table - 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
IDC_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_DEV_INFANT_MICKOENV_TEMP_FATIENT_CHAN		MDC_DIM_DEGC	Cel	268192	•	•
. MDC_IEMP_SKIN	150388					•
NDO TEND OVIN CETTINO	40007004	MDC_DIM_FAHR	[degF]	266560		-
. MDC_TEMP_SKIN_SETTING	16927604	MDC_DIM_DEGC	Cel	268192	•	
	70210	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	1
					MANUAL	-
	70839					
IDC_DEV_INFANT_MICROENV_HEATER_CONVECTIVE_CHAN	10033		•	•		•
MDC_TEMP_MICROENV	184296	MDC_DIM_DEGC	Cel	268192		
	104230	MDC_DIM_BLGC		266560		•
NDO TEND MODOENIV OFTINO	40004540		[degF]			
. MDC_TEMP_MICROENV_SETTING	16961512	MDC_DIM_DEGC	Cel	268192		
	101007	MDC_DIM_FAHR	[degF]	266560	DADIANT	
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_DEV_INFANT_MICROENV_HOMIDITT_CHAN	184292	MDC_DIM_PERCENT	• %	262688		•
. MDC_REL_HUMIDITY_MICROENV_SETTING	16961508	MDC_DIM_PERCENT	%	262688	•	•
MDC_DEV_INFANT_MICROENV_02_CHAN	0	•	•			•
. MDC_CONC_02_MICROENV	184288	MDC_DIM_PERCENT	%	262688		
. MDC_CONC_02_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_02_VMD	69642					
MDC_DEV_ANALY_SAT_02_CHAN	69643					
. MDC_PULS_OXIM_SAT_02	150456	MDC_DIM_PERCENT	%	262688	· ·	
	149530	MDC_DIM_BEAT_PER_MIN	{beat}/min	264864		
MDC PULS OXIM PULS RATE			10000g/IIIII	201004		
MDC_PULS_OXIM_PULS_RATE		MDC_DIM_PER_MIN	{count}/min	264672		

#### 9 Annex A: Physiological Monitoring Profile

#### 9.1 Introduction and Purpose

The Physiological Monitoring Profile defined in this Annex effectively constrains the Harmonized Rosetta [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.

CMI has identified nine categories of observational identifiers related to physiological monitoring, comprising 206 of the 910 observational identifiers currently in hRTM. Of those 206 identifiers, 58 are representative of most physiological monitoring devices' capabilities and are on the critical path for the care of ICU patients and surgical intraoperative care. Accordingly, CMI has thoroughly reviewed these identifiers and provided additional clarity and disambiguation where needed.

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

These 58 baseline and 8 deprecated terms define CMI's 'Physiological Monitoring Profile' of hRTM. All 206 hRTM physiological monitoring identifiers have not been duplicated within this annex and are freely accessible through Rosetta Terminology Mapping tables hosed on the NIST website. Specifically the harmonized RTM table may be accessed at [hRTM]. Table 2 includes only those 58 identified in the profile. The baseline and deprecated terms are listed with the following columns REFID and CF\_CODE10, Common Term, Term Description and UCM\_UCUM columns. A CMI status column is marked 'V' or 'D' for "Validated" or "Deprecated" respectively. Except for the "CMI Category" column, which is created by CMI for subclassification, and the "CMI Status" column, content is copied verbatim from RTM database. The remaining columns associated with each of these identifiers may also be accessed through the [hRTM] table.

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.
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.

### 9.2 Terms and Definitions

Sampling Methodology	Description
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.
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)
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.

Sampling Methodology	Description
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.
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.
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.

Sampling Methodology	Description	
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. <i>Units: CO = L/min</i>
Stroke Volume	The volume of blood pumped by the heart in a single ventricular contraction or heartbeat.	$SV = \frac{CO}{HR}$ Units: $SV = \frac{mL}{beat}$

Sampling Methodology	Description	
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.	$PVR = \frac{(MPAP - PCWP) \times 80}{CO}$ 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. CMI supports use of the DeBois formula provided as one of 2 options by major vendors	$BSA = 0.007184 (W^{0.425} X H^{0.725})$ Units BSA = m <sup>2</sup> Wt = Kg Ht = cm
Cardiac Index	Cardiac Output normalized to an individual's size by body surface area.	$CI = \frac{CO}{BSA}$ $Units: CI = \frac{L/min}{m^2}$

Sampling Methodology	Description	
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.	$SVRI = \frac{(MAP - CVP) X  80}{CI}$
		$Units: SVRI = \frac{dyne.sec.m^2}{cm^5}$
		$PVRI = \frac{(MAP - PCWP) X 80}{CI}$
		$Units: PVRI = \frac{dyne.sec.m^2}{cm^5}$

# 9.3 Abbreviations and Acronyms

Abbreviations / Acronyms	Description
AP	Arterial Pressure
BP	Blood Pressure
BSA	Body Surface Area
CI	Cardiac Index
СО	Cardiac Output
CVP	Central Venous Pressure
DBP	Diastolic Blood Pressure
HR	Heart Rate
МАР	Mean Arterial Pressure
МРАР	Mean Pulmonary Arterial Pressure
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
SV	Stroke Volume
SVR	Systemic Vascular Resistance
SVRI	Systemic Vascular Resistance Index

# 9.4 Physiological Monitoring Observational Identifier Categories

CMI Category	Term Count
ECG Monitoring	38
Glasgow Coma Scale	6
Vital Signs & Hemodynamics	101
Pulse Oximetry	21
Core Temperature Sources	25
Intracranial Pressure Monitoring	5
Noninvasive Resp. Rate Monitoring	5
Transcutaneous Monitoring	4
Urine Volume Output	1
Total	206

## 9.5 hRTM Physiological Monitoring Profile

Not Part of hRT	M	Duplicated Verbatim from hRTM					
CMI-Category	CM I- Sta tus	REFID	CF_CO DE10	Commo n Term	Term Description	UOM_UCUM	
Body Attributes	V	MDC_AREA_BODY_SURF_AC TUAL	18874 4	Patient body surface area	The actual body surface area of the patient, calculated from patient actual weight and patient actual length.	m2	
ECG Rate & Rhythm	V	MDC_ECG_CARD_BEAT_RA TE	14784 2	heart rate	Rate of cardiac beats	/min 1/min {beat}/min {beats}/min	
ECG Rate & Rhythm	V	MDC_ECG_HEART_RATE	14784 2			/min 1/min {beat}/min {beats}/min	

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Not Part of hRTM

			-		
ECG Rate & Rhythm	V	MDC_ECG_V_P_C_CNT	14806 5	{beat} {beats} 1	L
ECG Rate & Rhythm	V	MDC_ECG_V_P_C_RATE	14806 6	/min 1/min {beat}/min {beats}/min	
ECG ST Monitoring	V	MDC_ECG_AMPL_ST_I	13184 1	mV uV	
ECG ST Monitoring	V	MDC_ECG_AMPL_ST_II	13184 2	mV uV	
ECG ST Monitoring	V	MDC_ECG_AMPL_ST_V1	13184 3	mV uV	
ECG ST Monitoring	V	MDC_ECG_AMPL_ST_V2	13184 4	mV uV	
ECG ST Monitoring	V	MDC_ECG_AMPL_ST_V3	13184 5	mV uV	
ECG ST Monitoring	V	MDC_ECG_AMPL_ST_V4	13184 6	mV uV	
ECG ST Monitoring	V	MDC_ECG_AMPL_ST_V5	13184 7	mV uV	
ECG ST Monitoring	V	MDC_ECG_AMPL_ST_V6	13184 8	mV uV	
ECG ST Monitoring	V	MDC_ECG_AMPL_ST_III	13190 1	mV uV	
ECG ST Monitoring	V	MDC_ECG_AMPL_ST_AVR	13190 2	mV uV	
ECG ST Monitoring	V	MDC_ECG_AMPL_ST_AVL	13190 3	mV uV	
ECG ST Monitoring	V	MDC_ECG_AMPL_ST_AVF	13190 4	mV uV	

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		Dupricated verbatin if on interm						
Hdyn-ArtBP	V	MDC_PRESS_BLD_NONINV	15002 0			kPa mm[Hg]		
Hdyn-ArtBP	V	MDC_PRESS_BLD_NONINV_ SYS	15002 1	Noninvas ive systolic blood pressure	Pressure of the blood, obtained noninvasively (i.e., fingertip), at the systolic phase	kPa mm[Hg]		
Hdyn-ArtBP	V	MDC_PRESS_BLD_NONINV_ DIA	15002 2	Noninvas ive diastolic blood pressure	Pressure of the blood, obtained noninvasively (i.e., fingertip), at the diastolic phase	kPa mm[Hg]		
Hdyn-ArtBP	V	MDC_PRESS_BLD_NONINV_ MEAN	15002 3	Noninvas ive mean blood pressure	Pressure of the blood, obtained noninvasively (i.e., fingertip), as computed by averaging on one cycle	kPa mm[Hg]		
Hdyn-ArtBP	V	MDC_PRESS_BLD_ART	15003 2	Arterial pressure	Pressure of the blood in an artery	kPa mm[Hg]		
Hdyn-ArtBP	V	MDC_PRESS_BLD_ART_SYS	15003 3	Systolic arterial pressure	Systolic pressure of the blood in an artery	kPa mm[Hg]		
Hdyn-ArtBP	V	MDC_PRESS_BLD_ART_DIA	15003 4	Diastolic arterial pressure	Diastolic pressure of the blood in an artery	kPa mm[Hg]		
Hdyn-ArtBP	V	MDC_PRESS_BLD_ART_MEA N	15003 5	Mean arterial pressure	Mean pressure of the blood in an artery	kPa mm[Hg]		
Hdyn-ArtBP	V	MDC_PRESS_BLD_ART_ABP	15003 6			kPa mm[Hg]		
Hdyn-ArtBP	V	MDC_PRESS_BLD_ART_ABP _SYS	15003 7			kPa mm[Hg]		
Hdyn-ArtBP	V	MDC_PRESS_BLD_ART_ABP _DIA	15003 8			kPa mm[Hg]		

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Hdyn-ArtBP	V	MDC_PRESS_BLD_ART_ABP _MEAN	15003 9			kPa mm[Hg]
Hdyn-ArtBP	D	MDC_PRESS_BLD	15001 6	Blood pressure	Pressure of the blood	kPa mm[Hg]
Hdyn-ArtBP	D	MDC_PRESS_BLD_SYS	15001 7	Systolic blood pressure	Pressure of the blood at the systolic phase	kPa mm[Hg]
Hdyn-ArtBP	D	MDC_PRESS_BLD_DIA	15001 8	Diastolic blood pressure	Pressure of the blood at the diastolic phase	kPa mm[Hg]
Hdyn-ArtBP	D	MDC_PRESS_BLD_MEAN	15001 9	Mean blood pressure	Pressure of the blood as computed by averaging on one cycle	kPa mm[Hg]
Hdyn-ArtBP	D	MDC_PRESS_CUFF	15030 0			kPa mm[Hg]
Hdyn-ArtBP	D	MDC_PRESS_CUFF_SYS	15030 1	Disconti nuous, noninvas ive systolic blood pressure	Pressure of the blood at the systolic phase, measured discontinuously and noninvasively (cuff)	kPa mm[Hg]
Hdyn-ArtBP	D	MDC_PRESS_CUFF_DIA	15030 2	Disconti nuous, noninvas ive diastolic blood pressure	Pressure of the blood at the diastolic phase, measured discontinuously and noninvasively (cuff)	kPa mm[Hg]
Hdyn-ArtBP	D	MDC_PRESS_CUFF_MEAN	15030 3	Disconti nuous, noninvas ive mean blood pressure	Pressure of the blood computed as mean value between systolic and diastolic pressures, measured discontinuously and noninvasively (cuff)	kPa mm[Hg]

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Hdyn- CardOutput	V	MDC_OUTPUT_CARD	15027 6	Cardiac output	Quantity of blood pumped by the left ventricle into the aorta per minute	L/min	
Hdyn- CardOutput	V	MDC_OUTPUT_CARD_INDE X	14977 2	Cardiac index	Quantity of blood pumped by the left ventricle into the aorta per minute and divided by the body surface area (CO/BSA)	L/min/m2	
Hdyn- CardOutput	V	MDC_OUTPUT_CARD_CTS	15049 2	Continuo us cardiac output	Quantity of blood pumped by the left ventricle into the aorta per minute, obtained as continuous measurement	L/min	
Hdyn- CardOutput	V	MDC_OUTPUT_CARD_NONC TS	15049 6	Disconti nuous cardiac output	Quantity of blood pumped by the left ventricle into the aorta per minute, obtained as not continuous measurement	L/min	
Hdyn-CVP	V	MDC_PRESS_BLD_VEN_CEN T	15008 4	Central venous pressure	Pressure of the blood in the thoracic venae cavae	kPa mm[Hg]	
Hdyn-CVP	V	MDC_PRESS_BLD_VEN_CEN T_MEAN	15008 7	Mean central venous pressure	Mean pressure of the blood in the thoracic venae cavae	kPa mm[Hg]	
Hdyn- LVRVFctn	V	MDC_VOL_BLD_STROKE	15040 4	Stroke volume	Volume of blood ejected per beat	mL mL/{beat}	
Hdyn- LVRVFctn	V	MDC_VOL_BLD_STROKE_IN DEX	15063 6	Stroke Volume Index	Left-ventricular stroke volume per heartbeat, normalized for body surface area.	mL/m2	

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Hdyn-Pulse Rate	V	MDC_BLD_PULS_RATE_INV	14952 2	Invasive pulse rate	Rate of blood pulse in an artery, measured invasively	/min 1/min {count}/min /min 1/min {beat}/min {beats}/min /min 1/min {pulse}/min {pulses}/min
Hdyn-Pulse Rate	V	MDC_PULS_RATE_NON_INV	14954 6	Noninvas ive pulse rate	Rate of blood pulse in an artery, measured not invasively	/min 1/min {count}/min /min 1/min {beat}/min {beats}/min /min 1/min {pulse}/min {pulses}/min√
Hdyn-RtHrt & Pul Press	V	MDC_PRESS_BLD_ART_PUL M_SYS	15004 5	Systolic pulmona ry arterial pressure	Systolic pressure of the blood in the pulmonary artery.	kPa mm[Hg]
Hdyn-RtHrt & Pul Press	V	MDC_PRESS_BLD_ART_PUL M_DIA	15004 6	Diastolic pulmona ry arterial pressure	Diastolic pressure of the blood in the pulmonary artery	kPa mm[Hg]
Hdyn-RtHrt & Pul Press	V	MDC_PRESS_BLD_ART_PUL M_MEAN	15004 7	Mean pulmona ry arterial pressure	Mean pressure of the blood in the pulmonary artery	kPa mm[Hg]
Hdyn-RtHrt & Pul Press	V	MDC_PRESS_BLD_ART_PUL M_OCCL	15005 2	Pulmona ry artery wedge pressure	Pressure of the blood measured by a catheter wedged into a small branch of the pulmonary artery	kPa mm[Hg]
Hdyn-RtHrt & Pul Press	V	MDC_PRESS_BLD_ART_PUL M_WEDGE	15005 2	Pulmona ry artery wedge pressure	Pressure of the blood measured by a catheter wedged into a small branch of the pulmonary artery	kPa mm[Hg]
Hdyn-Vasc Resistance	V	MDC_RES_VASC_SYS_INDEX	14976 0	Systemic vascular resistanc e indexed	Difference between systemic and pulmonary resistance	dyn.s.m2/cm5 dyn.s.cm-5.m2

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Hdyn-Vasc Resistance	V	MDC_RES_VASC_PULM	15030 8	Pulmona ry vascular resistanc e	Resistance to blood flow in the pulmonary vessels	dyn.s/cm5 [PRU] mm[Hg].s/mL [wood'U] mm[Hg].min/L
Hdyn-Vasc Resistance	V	MDC_RES_VASC_SYS	15031 2	Systemic vascular resistanc e	Resistance to blood flow in the systemic circulation	dyn.s/cm5 [PRU] mm[Hg].s/mL [wood'U] mm[Hg].min/L
Hdyn-Vasc Resistance	V	MDC_RES_VASC_PULM_IND EX	15285 2	Pulmona ry Vascular Resistan ce Index	Pulmonary Vascular Resistance Index, normalized with respect to body surface area	dyn.s.m2/cm5 dyn.s.cm-5.m2
Pulse Ox Measures	V	MDC_PULS_OXIM_PULS_RA TE	14953 0			/min 1/min {count}/min /min 1/min {beat}/min {beats}/min /min 1/min {pulse}/min {pulses}/min
Pulse Ox Measures	V	MDC_PULS_OXIM_SAT_02	15045 6			%
RR-NonInv	V	MDC_TTHOR_RESP_RATE	15157 8	Respirati on rate	Rate of breathing; method: transthoracic impedance variations	/min 1/min {breath}/min {breaths}/min {resp}/min
Temp	V	MDC_TEMP_FOLEY	15034 8			Cel [degF]
Тетр	V	MDC_TEMP	15034 4			Cel Cel{delta} [degF] [degF]{delta}
Тетр	V	MDC_TEMP_AWAY	15035 6			Cel [degF]
Тетр	V	MDC_TEMP_CORE	15036 8			Cel [degF]
Тетр	V	MDC_TEMP_ESOPH	15037 2			Cel [degF]

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			-	
Temp	V	MDC_TEMP_NASOPH	15038	Cel
			0	
				[degF]
Temp	V	MDC_TEMP_SKIN	15038	Cel
			8	
				[degF]

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### 10 Annex B: Ventilation and Anesthesia Profile

### **10.1 Introduction and Purpose**

The development medical device semantics and ventilators specifically has been within the domain of the manufacturers and IEEE. The SDOs have operated within the ISO/IEEE community and separate from the clinical informatics community. Laudably IEEE has provided 15 years of thoughtful development consolidating and harmonizing terms that form the foundation of ventilator observational identifiers. Historically the ability to capture only rudimentary ventilator data led to minimal demand and limited to no involvement from healthcare professionals involved in informatics, quality metrics, systems engineering or T2 translational research.

Accordingly, it is not surprising that one finds within current medical literature descriptions of the challenges in the extraction of ventilator parameters utilized in the management pulmonary disease and the associated alterations in lung mechanics for research, quality management and effective controls on variation in care and implementation of ventilator management and weaning protocols across multiple manufacturers and models. Further complicating the broad semantic landscape that describes the domain of mechanical ventilation is the proprietary terminology that describes both conventional and novel ventilator modes allowing for the convenient presetting of increasingly complex configurations of ventilator parameters made possible by the digital processors now driving new ventilator technology.

## **10.2 The Mechanical Ventilation Semantic Working Group**

Newer ventilators and anesthesia machines with are capable of delivering much more sophisticated observations. The IEEE has responded by expanding ventilator semantic observations by two-fold from their original work in 2004. The 11073 – 10101a annex published in 2015 was a major update in the terminology and these observations now constitute approximately 50% of the 900+ terms that define the medical device semantic space in 11073 described within the harmonized Rosetta Terminology Management archive, [hRTM].

To to take advantage of this recent work CMI established a Semantic Working Group to assure a profile would satisfy the needs of the medical community for effective patient management, quality improvement and clinical research. The working group was comprised of the following professional disciplines internists, intensivists, pulmonary medicine / critical care, neonatology, anesthesiologists, clinical informaticists, biomedical engineers and computer scientists. These new observations are highly specified and well defined. The ventilator data now identified creates opportunities for monitoring, measurement and research previously unavailable.

## **10.3 Scope of Observational Identifiers**

The 956 harmonized rosetta terms were filtered to only include those from table A.7.4.8 in the 2015 10101a Amendment. These 432 observations represent those identified with ventilator and anesthesia functionality. The list was narrowed through attrition by the following criteria. Exclusions:

- Observations of respiratory rate absent not originating from a mechanical ventilator
- POC measures of arterial blood gases measurements
- Anesthetic gas delivery and gas concentration observations
- Anesthesia specific observations

This resulted in a field of 285 ventilator related observations from which 99 were identified as core to ventilator management and weaning.

The semantic working group narrowed the list to 68 making up a profile to support mechanical ventilator management. We would anticipate future additions to this annex and as more sophisticated ventilator functions and the need for sequential ventilator adjustment comes under evaluation.

These 68 observations are listed below with columns similar to those identified for the presentation of physiologic monitor observations.

Early indications are that some devices continue to output legacy observations published in 2004. The goal of this Annex is to identify those ventilator observations that describe a parameter with the least ambiguity and the greatest specificity as they are represented in both 11073-10101a 2015 and those additions approved in 11073-10101R, 2018 (yet to be unpublished). Those new and/or more highly specified parameters have been designated as the primary or preferred term while the historic synonym is retained as an alternate to accommodate legacy equipment. This is consistent with the recommendations of IEEE that is selecting 2015 codes as the best choice for any class of measures designating 2004 synonymous codes as alternates.

In some cases these updated identifiers have been designated as "True Synonyms" (i.e. both observations have the same CF\_CODE10 number. When this occurs the synonyms are represented within the same field, primary in the first position, secondary italicized in the second position. in support of transition to the newer codes in the future some of these synonyms are recommended for deprecation. All of the parameters can be reviewed within the harmonized Rosetta data set at [hRTM].

# **10.4 Terms and Definitions**

Term / Abbreviation	Definition
airway pressure	The pressure at the airway opening measured relative to atmospheric pressure during mechanical ventilation.
airway pressure release ventilation (APRV) .	A form of pressure control intermittent mandatory ventilation that is designed to allow unrestricted spontaneous breathing throughout the breath cycle. APRV is applied using I:E ratios much greater than 1:1 and usually relying on short expiratory times and gas trapping to maintain end expiratory lung volume rather than a preset PEEP. This is in contrast to Bilevel Positive Airway Pressure (BIPAP) which is also pressure control intermittent mandatory ventilation but with I:E ratios closer to 1:1, expiratory times that do not create significant gas tapping and preset PEEP levels above zero
assisted breath	A breath during which all or part of inspiratory (or expiratory) flow is generated by the ventilator doing work on the patient. In simple terms, if the airway pressure rises above end expiratory pressure during inspiration, the breath is assisted (as in the Pressure Support mode). It is also possible to assist expiration by dropping airway pressure below end expiratory pressure. In contrast, spontaneous breaths during CPAP are unassisted because the ventilator attempts to maintain a constant airway pressure during inspiration.
autoPEEP	The positive difference between end-expiratory alveolar pressure (total or intrinsic PEEP) and the end-expiratory airway pressure (set or extrinsic PEEP; Am J Respir Crit Care Med 2011;184:756-762). When autoPEEP exists, a positive pressure difference drives flow throughout exhalation until the subsequent breath interrupts deflation. AutoPEEP is caused when expiratory time (either set by the patient's brain or a ventilator) is short relative to the expiratory time constant of the respiratory system (possibly including the expiratory resistance of the breathing circuit).
automatic tube compensation	A feature that allows the operator to enter the size of the patient's endotracheal tube and have the ventilator calculate the tube's resistance and then generate just enough pressure (in proportion to inspiratory or expiratory flow) to compensate for the added resistive load.

Term / Abbreviation	Definition
breath	A positive change in airway flow (inspiration) paired with a negative change in airway flow (expiration), associated with ventilation of the lungs. This definition excludes flow changes caused by hiccups or cardiogenic oscillations. However, it allows the superimposition of, for example, a spontaneous breath on a mandatory breath or vice versa. The flows are paired by size, not necessarily by timing. For example, in Airway Pressure Release Ventilation there is a large inspiration (transition from low pressure to high pressure) possibly followed by a few small inspirations and expirations, followed finally by a large expiration (transition from high pressure to low pressure). These comprise several small spontaneous breaths superimposed on one large mandatory breath. In contrast, during High Frequency Oscillatory Ventilation, small mandatory breaths are superimposed on larger spontaneous breaths.
breathing circuit	System of tubing connecting the patient to the ventilator.
breath sequence	A particular pattern of spontaneous and/or mandatory breaths. The 3 possible breath sequences are: continuous mandatory ventilation, (CMV), intermittent mandatory ventilation (IMV), and continuous spontaneous ventilation (CSV).
compliance	A mechanical property of a structure such as the respiratory system; a parameter of a lung model, or setting of a lung simulator; defined as the ratio of the change in volume to the associated change in the pressure difference across the system. Compliance is the reciprocal of elastance.
continuous mandatory ventilation	Commonly known as "Assist/Control"; CMV is a breath sequence for which spontaneous breaths are not possible between mandatory breaths because every patient trigger signal in the trigger window produces a machine cycled inspiration (ie, a mandatory breath). Machine triggered mandatory breaths may be delivered at a preset rate. Therefore, in contrast to IMV, the
	mandatory breath frequency may be higher than the set frequency but never
	below it. In some pressure controlled modes on ventilators with an active exhalation valve, spontaneous breaths may occur during mandatory breaths, but the defining characteristic of CMV is that spontaneous breaths are not permitted between mandatory breaths. See mandatory breath, intermittent
	mandatory ventilation, trigger window

CPAPContinuous positive airway pressure; the set or measured mean value of transrespiratory system pressure during unassisted breathing or between assisted breaths. While this term is sometimes used synonymously for PEEP, historically, PEEP came first. PEEP mechanisms originally required the patient to drop transrespiratory system pressure to below atmospheric pressure to inhale, imposing a load and causing an increased work of breathing. CPAP mechanisms were developed so that the patient only had to drop pressure below the set CPAP level to inhale, thus decreasing the imposed load. See PEEP.continuousA breath sequence for which all breaths are spontaneous.
<b>continuous</b> A breath sequence for which all breaths are spontaneous.
spontaneous ventilation
control variableThe variable (ie, pressure or volume in the equation of motion) that the ventilator uses as a feedback signal to manipulate inspiration. For simple set- point targeting, the control variable can be identified as follows: If the peak inspiratory pressure remains constant as the load experienced by the 
<b>CSV</b> See continuous spontaneous ventilation; all breaths are spontaneous. See spontaneous breath.
cycle (cycling)To end the inspiratory time (and begin expiratory flow)
cycle variableThe variable (usually pressure, volume, flow, or time) that is used to endinspiratory time (and begin expiratory flow).
elastanceA mechanical property of a structure such as the respiratory system; a parameter of a lung model, or setting of a lung simulator; defined as the ratio of the change in the pressure difference across the system to the associated change in volume. Elastance is the reciprocal of compliance.
expiratory timeThe period from the start of expiratory flow to the start of inspiratory flow; expiratory time equals expiratory flow time plus expiratory pause time.

Term / Abbreviation	Definition
flow triggering	The starting of inspiratory flow due to a patient inspiratory effort that generates inspiratory flow above a preset threshold (ie, the trigger sensitivity setting).
flow target	Inspiratory flow reaches a preset value that may be maintained before inspiration cycles off.
flow cycling	The ending of inspiratory time due to inspiratory flow decay below a preset threshold (aka, the cycle sensitivity).
IMV	See intermittent mandatory ventilation.
inspiratory flow	The flow into the airway opening during the inspiratory time. By convention, inspiratory flow is in the positive direction (above zero) in graphs.
inspiratory flow time	The period from the start of inspiratory flow (into the airway opening) to the cessation of inspiratory flow.
inspiratory hold	An intentional maneuver during mechanical ventilation whereby exhalation is delayed for a preset time (inspiratory hold time) after an assisted breath. This maneuver is used to assess static respiratory system mechanics and also to increase mean airway pressure during volume control ventilation in an attempt to improve gas exchange.
inspiratory hold (pause) time	The period from the cessation of inspiratory flow (into the airway opening) to the start of expiratory flow during mechanical ventilation.
inspiratory pressure	General term for the pressure at the patient connection during the inspiratory phase.
inspiratory pressure change	The change in transrespiratory system pressure associated with delivery of the tidal volume as described in the equation of motion for the respiratory
pressure change	system. For pressure control modes, if inspiratory pressure is set relative to atmospheric pressure, the term "peak inspiratory pressure" is used to describe the setting. If inspiratory pressure is set relative to PEEP, the term "inspiratory pressure change" is used. See equation of motion for the respiratory system, peak inspiratory pressure
inspiratory time	The period from the start of inspiratory flow to the start of expiratory flow. Inspiratory time equals inspiratory flow time plus inspiratory pause time.

Term / Abbreviation	Definition
intermittent mandatory ventilation	Breath sequence for which spontaneous breaths are permitted between mandatory breaths. For most ventilators, a short "window" is opened before the scheduled machine triggering of mandatory breaths to allow synchronization with any detected inspiratory effort on the part of the patient. This is referred to as synchronized IMV (or SIMV).
	Three common variations of IMV are: (1) Mandatory breaths are always delivered at the set frequency; (2) Mandatory breaths are delivered only when the spontaneous breath frequency falls below the set frequency; (3) Mandatory breaths are delivered only when the spontaneous minute ventilation (ie, product of spontaneous breath frequency and spontaneous breath tidal volume) drops below a preset or computed threshold (aka Mandatory Minute Ventilation). Therefore, in contrast to CMV, with IMV the mandatory breath frequency can never be higher than the set rate but it may be lower.
machine cycling	Ending inspiratory time independent of signals representing the patient determined components of the equation of motion (Pmus, elastance, or resistance). Common examples are cycling due to a preset tidal volume or inspiratory time. If a patient signal (indicating expiration) occurs during an inspiratory time synchronization window, inspiration stops and is defined as a machine cycled event that ends a mandatory breath. See machine triggering, patient triggering, synchronization window, trigger window, continuous mandatory ventilation, intermittent mandatory ventilation
machine triggering	Starting inspiratory flow based on a signal (usually time) from the ventilator, independent of a patient trigger signal. Examples include triggering based on a preset frequency (which sets the ventilatory period), or based on a preset minimum minute ventilation (determined by tidal volume divided by the ventilatory period). If a signal from the patient (indicating an inspiratory
	effort) occurs within a synchronization window, the start of inspiration is defined as a machine trigger event that begins a mandatory breath. See
	machine cycling, patient triggering, synchronization window, trigger window, continuous mandatory ventilation, intermittent mandatory ventilation
mandatory breath	A breath for which the patient has lost control over timing. This means a breath for which the start or end of inspiration (or both) is determined by the ventilator, independent of the patient. That is, the machine triggers and/or cycles the breath. A mandatory breath can occur during a spontaneous breath (eg, High Frequency Jet Ventilation). A mandatory breath is, by definition, assisted. See assisted breath, spontaneous breath

Term / Abbreviation	Definition
mode of ventilation	A predetermined pattern of interaction between a patient and a ventilator, specified as a particular combination of control variable, breath sequence, and targeting schemes for primary and secondary breaths.
patient cycling	Ending inspiratory time based on signals representing the patient determined components of the equation of motion, (Pmus, elastance, or resistance). Common examples of cycling variables are peak inspiratory pressure and percent inspiratory flow. See machine triggering, machine cycling, patient triggering, synchronization window, trigger window, continuous mandatory ventilation, intermittent mandatory ventilation
patient triggering	Starting inspiration based on a patient signal occurring in a trigger window, independent of a machine trigger signal. Common examples of patient trigger variables are airway pressure drop below baseline and inspiratory flow due to patient effort.
PC-CMV	Pressure controlled continuous mandatory ventilation.
PC-IMV	Pressure controlled intermittent mandatory ventilation.
PC-CSV	Pressure controlled continuous spontaneous ventilation.
peak airway pressure	The maximum airway pressure during a mechanically assisted inspiration, measured relative to atmospheric pressure.
peak inspiratory pressure	The inspiratory pressure change that is set relative to atmospheric pressure during pressure control modes. See inspiratory pressure change
PEEP	Positive end expiratory pressure; the value of transrespiratory system pressure at end expiration. See CPAP
positive pressure ventilation	A type of assisted breathing for which transrespiratory pressure difference is generated by raising airway pressure above body surface pressure (usually equal to atmospheric pressure). Examples would be ventilation with intensive care or transport ventilators.

Term / Abbreviation	Definition
pressure control	A general category of ventilator modes for which pressure delivery is predetermined by a targeting scheme such that inspiratory pressure is either proportional to patient effort or has a particular waveform regardless of respiratory system mechanics. When inspiratory pressure is preset, we further specify that inspiration must start out with the preset pressure to avoid confusion with dual targeting that may switch from a preset flow to a preset pressure. See dual targeting scheme. According to the equation of motion, pressure control means that inspiratory pressure is predetermined as the independent variable so that volume and flow become the dependent variables. See volume control
pressure cycling	Inspiration ends (ie, expiratory flow starts) when airway pressure reaches a preset threshold.
Pressure Support:	The name of a mode using a set-point targeting scheme in which all breaths are pressure or flow triggered, pressure targeted, and flow cycled.
pressure triggering	The starting of inspiratory flow due to a patient inspiratory effort that generates an airway pressure drop below end expiratory pressure larger than a preset threshold (ie, the trigger sensitivity setting).
pressure target	Inspiratory pressure reaches a preset value before inspiration cycles off.
primary breaths	Mandatory breaths during CMV or IMV or spontaneous breaths during CSV.
resistance	A mechanical property of a structure such as the respiratory system; a parameter of a lung model, or setting of a lung simulator; defined as the ratio of the change in the pressure difference across the system to the associated change in flow.
resistive load	The pressure difference applied across a system (e.g., a container) that is related to a rate of change of the system's volume and/or the flow of fluid within or through the system. (For a linear system: resistance x flow, or, resistance x rate of change of volume; for a container, the effective resistance includes the mechanical (usually viscous) resistances of its structural components and the flow resistance of the fluid [gas or liquid] within it.)
secondary breaths	Spontaneous breaths during IMV.
sensitivity	The sensitivity setting of the ventilator is a threshold value for the trigger variable which, when met, starts inspiration. In other words, the sensitivity is the amount the trigger variable must change to start inspiratory flow. Sensitivity is sometimes used to refer to the cycle threshold.

Term / Abbreviation	Definition
spontaneous breath	A breath for which the patient retains substantial control over timing. This means the start and end of inspiration may be determined by the patient, independent of any machine settings for inspiratory time and expiratory time. That is, the patient both triggers and cycles the breath. Note that use of this definition for determining the breath sequence (ie, CMV, IMV, CSV) assumes normal ventilator operation. For example, coughing during VC-CMV may result in patient cycling for a patient triggered breath due to the pressure alarm limit. While inspiration for that breath is both patient triggered and patient cycled, this is not normal operation and the sequence does not turn into IMV. A spontaneous breath may occur during a mandatory breath (eg Airway Pressure Release Ventilation). A spontaneous breath may be assisted or unassisted. See assisted breath, mandatory breath
synchronized IMV (SIMV)	A form of IMV in which mandatory breath delivery is coordinated with patient effort. A synchronized breath is considered to be machine triggered. See
	intermittent mandatory ventilation
synchronization	A short period, at the end of a preset expiratory time or at the end of a preset
window	inspiratory time, during which a patient signal may be used to synchronize a mandatory breath trigger or cycle event to a spontaneous breath. If the patient signal occurs during an expiratory time synchronization window, inspiration starts and is defined as a machine triggered event. This is because the mandatory breath would have been time triggered regardless of whether the patient signal had appeared or not and because the distinction is necessary to avoid logical inconsistencies in defining mandatory and spontaneous breaths which are the foundation of the mode taxonomy. If inspiration is triggered in a synchronization window, the actual ventilatory period for the previous breath will be shorter than the set ventilatory period (determined by the set mandatory breath frequency). Some ventilators add the lost time to the next mandatory breath period to maintain the set frequency. Sometimes a synchronization window is used at the end of the inspiratory time of a pressure controlled, time cycled breath. If the patient signal occurs during such an inspiratory time synchronization (or something similar with a different name) that makes use of both expiratory and inspiratory synchronization windows. See intermittent mandatory ventilation, machine triggering, patient triggering, trigger window.
TC-IMV	Time controlled intermittent mandatory ventilation (eg, High Frequency Oscillatory Ventilation or Intrapulmonary Percussive Ventilation).

Term / Abbreviation	Definition
tidal volume	The volume of gas, either inhaled or exhaled, during a breath. The maximum value of the volume vs time waveform.
time cycling	Inspiratory time ends after a preset time interval has elapsed. The most common examples are a preset inspiratory time or a preset inspiratory pause time.
time constant	The time at which an exponential function attains 63% of its steady state value in response to a step input; the time necessary for inflated lungs to passively empty by 63%; the time necessary for the lungs to passively fill 63% during pressure controlled ventilation with a rectangular pressure waveform. The time constant for a passive mechanical system is calculated as the product of resistance and compliance and has units of time (usually expressed in seconds). Passive inhalation or exhalation is virtually complete after 5 time constants.
time control	A general category of ventilator modes for which inspiratory flow, inspiratory volume, and inspiratory pressure are all dependent on respiratory system mechanics. As no parameters of the pressure or flow waveform are preset, the only control of the breath is the timing, ie, inspiratory and expiratory times. Examples of this are high frequency oscillatory ventilation and Volumetric Diffusive Respiration.
tidal pressure	the change in trans-alveolar pressure (i.e., pressure in the alveolar region minus pressure in the pleural space, equivalent to elastance times volume in the equation of motion) associated with the inhalation or exhalation of a tidal volume.
total cycle time	Same as ventilatory period, the sum of inspiratory time and expiratory time.
total PEEP	The sum of autoPEEP and intentionally applied PEEP or CPAP. Synonymous with intrinsic PEEP.
time triggering	The starting of inspiratory flow due to a preset time interval. The most common example is a preset ventilatory frequency.
total ventilatory support	The ventilator provides all the work of breathing; muscle pressure in the equation of motion is zero. This is normally only possible if the patient is paralyzed or heavily sedated.
transairway pressure	Pressure at the airway opening minus pressure in the lungs (i.e., alveolar pressure).

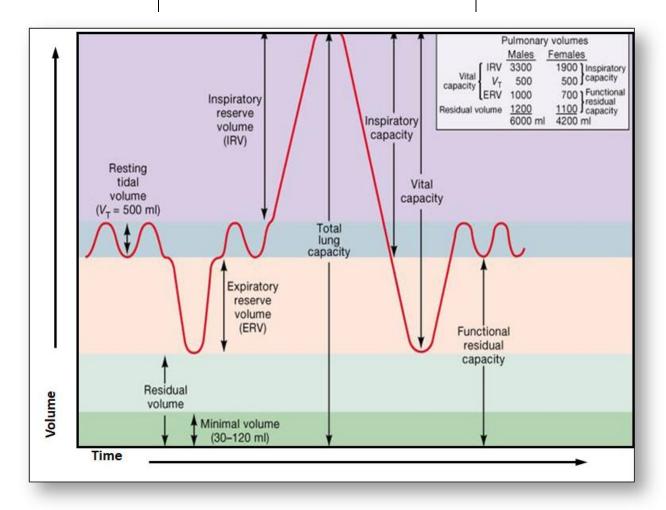
Term / Abbreviation	Definition
transalveolar	Pressure in the lungs minus pressure in the pleural space. Equal to
pressure	transpulmonary pressure only under static conditions.
trigger (triggering)	To start the inspiratory time. See machine triggering, patient triggering
trigger variable	The variable (usually pressure, volume, flow, or time) that is used to start the inspiratory time.
trigger window	The period comprised of the entire expiratory time minus a short "refractory" period required to reduce the risk of triggering a breath before exhalation is complete. If a signal from the patient (indicating an inspiratory effort) occurs within this trigger window, inspiration starts and is defined as a patient triggered event. See intermittent mandatory ventilation, machine triggering, patient triggering, synchronization window
ventilatory pattern	A sequence of breaths (CMV, IMV, or CSV) with a designated control variable (volume or pressure) for the mandatory breaths (or the spontaneous breaths for CSV).
ventilatory period	The time from the start of inspiratory flow of one breath to the start of inspiratory flow of the next breath; inspiratory time plus expiratory time; the reciprocal of ventilatory frequency. Also called total cycle time or total breath cycle.
volume control	A general category of ventilator modes for which both inspiratory flow and tidal volume are predetermined by a targeting scheme to have particular waveforms independent of respiratory system mechanics. Usually, flow and tidal volume may be set directly by the operator. Alternatively, the ventilator may determine tidal volume based on operator preset values for frequency and minute ventilation or the ventilator may determine inspiratory flow based on operator set tidal volume and inspiratory time. When inspiratory volume and flow are preset, we further specify that inspiration must start out with the preset flow to avoid confusion with dual targeting that may switch from a preset pressure to a preset flow and volume (eg. Volume Assured Pressure Support). See dual targeting scheme. Note that setting tidal volume is a necessary but not sufficient criterion for volume control. The reason is that some ventilators use pressure control with
volume cycling	Inspiratory time ends when inspiratory volume reaches a preset threshold (ie, tidal volume).
VC-CMV	Volume controlled continuous mandatory ventilation.
VC-IMV	Volume controlled intermittent mandatory ventilation.

Term / Abbreviation	Definition
volume target	A preset value for tidal volume that the ventilator is set to attain either within a breath or as an average over multiple breaths.
volume triggering	The starting of inspiratory flow due to a patient inspiratory effort that generates an inspiratory volume signal larger than a preset threshold (ie, the trigger sensitivity setting).
work of breathing	The general definition of work is the integral of pressure with respect to volume during an assisted inspiration. There are two general components of work related to mechanical ventilation. One kind is the work performed by the ventilator on the patient, which is reflected by a positive change in airway pressure above baseline during inspiration. The second component is the work the patient does on the ventilator to (eg, to trigger inspiration), which is reflected by a negative change in airway pressure below baseline during inspiration.

# 10.4.1 Pulmonary Volume and Capacity

Lung Volume / Capacity Measure	Definition	Representative Adult Value
Tidal Volume (VT)	The volume of air inspired/expired in a normal breath.	Approx. 500 mL
Inspiratory Reserve Volume (IRV)	The extra volume of air that may be inspired in excess of the VT.	Approx. 3,000 mL
Expiratory Reserve Volume (ERV)	The extra volume of air that may be expired in excess of the tidal volume.	Approx. 1,100 mL
Vital Capacity (VC)	Inspiratory reserve volume plus tidal volume plus expiratory reserve volume. VC = IRV + VT + ERV	Approx. 700 mL
Residual Volume (RV)	The volume of air remaining in lungs after forceful expiration.	Approx. 1,200 mL
Inspiratory Capacity (IC)	Tidal volume plus Inspiratory reserve volume. IC = VT + IR	Approx. 3,800 mL
Functional Residual Capacity (FRC)	Expiratory reserve volume plus residual volume. FRC = ERV + RV	Approx. 2,200 mL

Lung Volume / Capacity Measure	Definition	Representative Adult Value
<b>Total Lung Capacity</b>	Vital capacity plus residual volume. TLC = VC +	Approx. 6,000 mL
(TLC)	RV	
Minute Ventilation	Tidal Volume times the respiratory rate. MV =	MV = 500  mL/B X  12
(MV)	VT + RR	B/Min = 6L/Min



## **10.4.2 Inspiratory Breath Type Classifications**

In order to classify ventilator and patient interaction in response to a patient's breathing effort, a set of five observed breath-types: controlled, synchronized assisted, assisted, supported and unassisted have been provided with codes to differentiate specific REFID observations by individual or a group of breath types. Numeric observations such as breath rate, minute volume, and tidal volume reported by ventilators may be based on these breath types. In present-day ventilators, breaths are often classified either as spontaneous, assisted or controlled.

11073 and ISO/TC121/SC4 Working Groups have defined more specific rate and volume observations. Measurements qualified in this manner may be used to characterize the breathing

patterns of the ventilated patient and obtain an indication of the degree of patient dependence on the ventilator.

Although legacy 'spontaneous' terms may be used when detailed { P, S, A, Z, C } information is not available. The newer '\_BTSD' breath and inflation types should be used whenever possible. Additional breath rate examples and { P, S, A, Z, C} encodings are provided in 11073-10101a 2015 Annex D, Table A7.4.6.

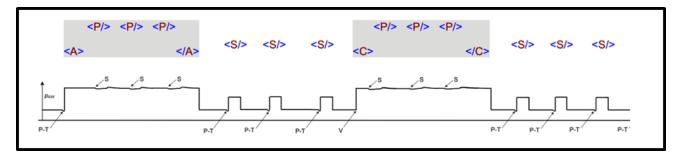
SD Codes	Breath Type Description and Examples
Р	The ventilator performs no action on behalf of the patient: breaths or inspiratory gas flow are initiated and terminated by the patient where pressure and flow/volume delivery are determined by the patient without support or assistance by the ventilator. Includes unassisted breaths that are superimposed on the intermittently elevated baseline pressure with APRV, bilevel or spontaneous-only modes (see Note 1).
S	Ventilator inflations or inspiratory gas flow that are initiated by the patient and that are intended to be terminated by the patient where the inspiratory pressure is raised above baseline to support some portion of the work of breathing (WOB). Includes proportional assist ventilation (PAV) where the ventilator provides a level of support proportional to patient effort. Includes supported breaths that are superimposed on the intermittently elevated baseline pressure with APRV, bilevel or spontaneous-only modes.
Α	Primary inflations that are initiated by the patient at greater than the set rate (see Note 2). The associated breaths are classified as having been assisted by the inflation.
Z	Primary inflations that have been assured to be delivered at the average set rate but which are initiated by the patient within a timed synchronization window. The associated breaths are classified as having had synchronized assistance by the inflation.
С	Primary inflations that are initiated by the ventilator at the set rate. The resulting breaths are classified as being controlled by the inflation. This includes backup ventilation breaths, apnea ventilation breaths and APRV and bilevel baseline pressure changes.

NOTE 1— APRV (Airway Pressure Relief Ventilation) or bilevel refer to ventilation modes where the baseline pressure is changed from time to time while allowing the patient to initiate either unassisted or supported breaths superimposed above the current baseline pressure level.

NOTE 2— A primary inflation is a ventilator inflation type that has been selected for assured delivery at or greater than the set rate according to the selected mode. The selected inflation type will be one that is intended to be terminated by the ventilator if not initiated by the patient.

Below: SD-codes can be used to delineate ventilator inflations and the inspiratory phase of patient breaths by encoding them as XML element nodes. For example, the airway pressure waveform for 'Bi-Level' ventilation mode is demonstrated with unassisted spontaneous patient <P/> breaths and

<S/> support inflations superimposed above the assisted <A/>, synchronized assisted <Z/>, and controlled <C/> primary inflations and expiratory phase.



P-T patient-trigger initiation of inflation (following detection of patient initiation of spontaneous breath)

- V ventilator initiation of inflation
- S patient initiation of unassisted spontaneous breath

Inspiratory breath or inflation type	Unassisted	Supported	Assisted		Controlled	_PSAZC
Breath Types	Р	S	A	Z	С	-
ventilator-initiated inflation rate					С	_C
patient-initiated primary-inflation rate			A	Z		_AZ
unassisted (patient-initiated) breath rate	Р					_P
patient-initiated inflation rate		S	A	Z		_SAZ
patient-initiated support-inflation rate		S				_S
(total) inflation rate		S	A	Z	С	_SACZ
patient-initiated rate	Р	S	A	Z		_PSAZ
patient-initiated concurrent-inflation rate		iS				_iS
unassisted concurrent-breath rate	iP					_iP
total respiratory rate	Р	S	A	Z	С	_PSAZC
unassisted and supported breath rate	Р	S				_PS
traditional "spontaneous" breath rate	Р	S				_PS
traditional "mandatory" breath rate			A	C	Z	_ACZ

# 10.4.3 Ventilator Observations Under Evaluation by IEEE Classification

### Ventilator Observations Under Evaluation by IEEE Classification

IEEE Category	Observations Included
1. Respiratory Rates - Method Specific	2
2. Vent Resp & Inflation Rates	6
3. Phase and Time Intervals	7
4. Airway Measured Flow	
5. Ventilator Measured Flow and Settings	1
6. Tidal Volume (Airway & Vent)	8
7. Minute Volume (Airway & Vent = vol/min)	3
8. Minute Volume (Adap Support Ref Value)	
9. Other Volumes	1
10. Airway & Other Pressures	4
11. Vent and Airway Pressures	5
12. Pressure Limits	
13. Pressure Risetimes	2
14. Plateau Pressure	3
15. Resistance & Compliance	2
16. PEEP	6
17. Apnea	2
18. Patient Vent Sychronization	3
19. Metabolics	
20. Work of Breathing	
21. Insp Pressure Time Product	
22. Tube Compensation	
23. Miscellaneous	1

## Ventilator Observations Under Evaluation by IEEE Classification

24. Ventilator Mode	2
25. Gas Flow	
26. Gas Conc. and Partial Press	7
27. High Frequency Ventilation	3
Total	68

## **10.5 hRTM Ventilator Management Profile**

Key for CMI Status Column	Key Definitions
1	Indicates the primary observation identifier
2	Indicates an alternate or secondary observation identifier *
0	Indicates the observation has been recommended for deprecation by CMI

\* When present, primary and secondary observational identifiers we be listed sequentially with the secondary term subordinate.

IEEE Category	CMI Stat us	REFID	CF_COD E10	Common Term	Term Description
1. Respirator y Rates - Method Specific	1	MDC_RESP_BTSD_PS_RATE	151674	Spontaneous respiration rate (preferred)	Spontaneous respiration rate, the rate of breaths or inspiratory gas flow initiated by the patient where flow and/or volume is determined by the patient and are delivered with the intention that the breath will be terminated by the patient.
1. Respirator y Rates - Method Specific	2	MDC_AWAY_RESP_RATE	151570	Respiration rate	Rate of breathing; method: direct airway flow measurement.
2. Vent Resp & Inflation Rates	1	MDC_VENT_RESP_RATE_SETTING	1692880 2	Set inflation rate	Displayed minimum and/or actual ventilator rate setting, may be mode dependent.
2. Vent Resp & Inflation Rates	1	MDC_VENT_RESP_RATE_AVG_SETTING MDC_VENT_RESP_RATE_MEAN_SETTING	1692880 5	Average ventilation rate setting	Average ventilator-initiated inflation rate, e.g. in Synchronized Intermittent Mandatory Ventilation (SIMV) ventilation mode.
2. Vent Resp & Inflation Rates	1	MDC_VENT_RESP_BTSD_PSAZ_RATE	152554	Patient- initiated breath rate	Rate of breaths or inspiratory gas flow initiated by the patient that are unassisted or delivered as supported, assisted or synchronized assisted breaths.
2. Vent Resp & Inflation Rates	1	MDC_VENT_FLOW_RESP_RATE	151626	Ventilation rate	Rate of mechanical ventilation, method: volume/flow relation (comment: pediatric)
2. Vent Resp & Inflation Rates	1	MDC_VENT_PRESS_RESP_RATE	151618	Ventilation rate	Rate of mechanical ventilation; method: pressure measurement
2. Vent Resp & Inflation Rates	1	MDC_VENT_SIGH_RATE	151634	Ventilation sigh number	Number of sighs delivered per minute during mechanical ventilation
3. Phase and Time Intervals	1	MDC_TIME_PD_EXP	152612	Expiratory time	Duration of an expiratory phase
3. Phase and Time Intervals	1	MDC_TIME_PD_INSP	152608	Inspiratory time	Duration of an inspiratory phase

IEEE Category	CMI Stat us	REFID	CF_COD E10	Common Term	Term Description
3. Phase and Time Intervals	1	MDC_VENT_TIME_PD_INSP_SETTING	1692963 2	Inspiratory time setting	
3. Phase and Time Intervals	1	MDC_RATIO_IE	151832	Ratio inspiration expiration time	Ratio of durations of inspiratory and expiratory phases.
3. Phase and Time Intervals	1	MDC_RATIO_IE_SETTING	1692904 8		
3. Phase and Time Intervals	1	MDC_VENT_TIME_PD_EXP_HOLD	152636		Duration for an expiratory hold, a ventilator function intended to temporarily maintain a constant lung volume during a set extension of the expiratory phase.
5. Ventilator Measured Flow and Settings	2	MDC_VENT_FLOW_INSP	151948	Ventilation inspiratory flow	Inspiratory gas flow in airway during mechanical ventilation
6. Tidal Volume (Airway & Vent)	1	MDC_VOL_AWAY_TIDAL_PER_IBW	153208	Tidal volume per body mass	Volume of gas leaving the patient through the patient connection port, normalized by the patient,Äôs ideal body weight (typ kg), reported individually or as an average for all breath types.
6. Tidal Volume (Airway & Vent)	2	MDC_VOL_AWAY_TIDAL_PER_IBW_SETTIN G	1693060 4		
6. Tidal Volume (Airway & Vent)	1	MDC_VOL_AWAY_TIDAL_EXP	152664	Expired Tidal Volume	Volume of expired gas for each breath, breath type(s) not specified. [This term may be used with legacy devices and systems where the breath types are unknown; otherwise, the more precise term MDC_VOL_AWAY_TIDAL_EXP_BTS D_PSAZC should be used.]
6. Tidal Volume (Airway & Vent)	1	MDC_VOL_AWAY_TIDAL_EXP_BTSD_PSAZC _PER_IBW	152668	Expired Tidal Volume per body mass	Volume of expired gas for all breath and inflation types, normalized by the patient,Äôs ideal body weight (typ kg),
		MDC_VOL_AWAY_TIDAL_EXP_PER_IBW		(for all breath types)	reported individually or as an average.

IEEE Category	CMI Stat us	REFID	CF_COD E10	Common Term	Term Description
6. Tidal Volume (Airway & Vent)	1	MDC_VOL_AWAY_TIDAL_EXP_BTSD_PS	152676	Expired Tidal Volume for unassisted or supported (aka spontaneous) breaths	Volume of expired gas for unassisted or supported (aka spontaneous) breaths.
6. Tidal Volume (Airway & Vent)	0	MDC_VENT_VOL_TIDAL	151980	Ventilation tidal volume	Volume of gas delivered through the patient-connection port during a respiratory cycle
6. Tidal Volume (Airway & Vent)	1	MDC_VENT_VOL_TIDAL_SETTING	1692919 6	Tidal volume setting	
6. Tidal Volume (Airway & Vent)	1	MDC_VENT_VOL_TIDAL_INSP_SETTING	1693043 6	Inspired tidal volume setting	
7. Minute Volume (Airway & Vent = vol/min)	2	MDC_VOL_MINUTE_AWAY	151880	Minute volume	Total volume of gas breathed in 1 min
7. Minute Volume (Airway & Vent = vol/min)	1	MDC_VOL_MINUTE_AWAY_EXP	151884	Expired Minute volume	Volume of gas per minute leaving the patient's airway during expiratory phases. [This term may be used with legacy devices and systems where the breath types are unknown; otherwise, the more precise term MDC_VOL_MINUTE_AWAY_EXP_B TSD_PSAZC should be used.]
7. Minute Volume (Airway & Vent = vol/min)	1	MDC_VOL_MINUTE_AWAY_EXP_BTSD_PSAZ C	152692	Expired minute volume (total for all breath types)	Volume of expired gas per minute for all breath and inflation types (total).
9. Other Volumes	1	MDC_CAPAC_VITAL	151680	Vital capacity	Difference in volume between maximum inspiration and maximum expiration
10. Airway & Other Pressures	1	MDC_PRESS_AWAY_MAX	151793	Maximum airway pressure	Peak pressure of gas in airway
10. Airway & Other Pressures	1	MDC_PRESS_AWAY_CTS_POS	151796	CPAP pressure	Continuous pressure in airway during spontaneous respiration

IEEE Category	CMI Stat us	REFID	CF_COD E10	Common Term	Term Description
10. Airway & Other Pressures	1	MDC_PRESS_AWAY_INSP	151816	Inspiratory airway pressure	Pressure of gas in airway during inspiration
10. Airway & Other Pressures	1	MDC_PRESS_AWAY_INSP_MAX	151817	Maximum inspiratory airway pressure (peak inspiratory pressure)	Maximum pressure of gas in airway during inspiration
11. Vent and Airway Pressures	1	MDC_VENT_PRESS_AWAY_MAX	151973		Maximum inspiratory airway pressure
11. Vent and Airway Pressures	1	MDC_VENT_PRESS_AWAY_MIN	151974		Minimum inspiratory airway pressure
11. Vent and Airway Pressures	1	MDC_VENT_PRESS_AWAY_MEAN	151975		Mean inspiratory airway pressure
11. Vent and Airway Pressures	1	MDC_VENT_PRESS_AWAY_SETTING	1692918 8		Inspiratory airway pressure setting.
11. Vent and Airway Pressures	1	MDC_VENT_PRESS_AWAY_SUPP	152732	Pressure for support inflations	The inspiratory airway pressure for pressure support inflations.
13. pressure Risetimes	1	MDC_VENT_PRESS_AWAY_RISETIME_CTLD _SETTING	1692998 4		
13. pressure Risetimes	1	MDC_VENT_PRESS_AWAY_RISETIME_CTLD _PERCENT	153260	Rise time percent	The time for pressure to reach a preset fraction of the set inspiratory pressure for controlled inflations, expressed as a percentage of the duration of the inspiratory phase.
14. Plateau Pressure	1	MDC_PRESS_RESP_PLAT MDC_PRESS_RESP_PLAT_STATIC	151784	Plateau pressure	Airway pressure during an inspiratory-hold procedure or during a flow pause in a pressure control inflation
14. Plateau Pressure	1	MDC_PRESS_RESP_PLAT_DYNAMIC	152776	Dynamic Plateau Pressure	The estimated airway pressure that would have occurred during an inspiratory-hold or during a flow pause in a pressure control inflation.

IEEE Category	CMI Stat us	REFID	CF_COD E10	Common Term	Term Description
14. Plateau Pressure	1	MDC_VENT_PRESS_OCCL_NIF	152784	Negative Inspiratory Force (NIF)	The maximum negative airway pressure generated during an occluded inspiration arising from a Negative Inspiratory Force (NIF) maneuver
15. Resistance & Complia nce	1	MDC_COMPL_LUNG_DYN	151692	Thoracic compliance	Change of tidal volume per unit change of transthoracic pressure
15. Resistance & Complia nce	1	MDC_COMPL_LUNG_STATIC	151696	Lung compliance, static	Change of tidal volume per unit change in esophageal pressure measured statically at expiration end
16. PEEP	1	MDC_PRESS_AWAY_END_EXP_POS_INTRIN SIC	151808	Intrinsic PEEP (aka Auto P EEP)	The component of alveolar pressure in the lungs above extrinsic PEEP due to physiologic causes at the end of expiration.
16. PEEP	1	MDC_PRESS_AWAY_END_EXP_POS_EXTRIN SIC_DYNAMIC	152792	Dynamic extrinsic PEEP	Dynamic extrinsic PEEP, the minimum pressure at or near the end of expiration, reflecting the set PEEP from the ventilator.
16. PEEP	1	MDC_PRESS_AWAY_END_EXP_POS_INTRIN SIC_DYNAMIC	152796	Dynamic intrinsic PEEP	Dynamic intrinsic PEEP, obtained during the short period between expiratory valve closure and flow arriving at the patient.
16. PEEP	1	MDC_PRESS_AWAY_END_EXP_POS_TOTAL_ DYNAMIC	152800	Dynamic total PEEP	Dynamic total PEEP, obtained during the short period between expiratory valve closure and flow arriving at the patient.
16. PEEP	1	MDC_VENT_PRESS_AWAY_END_EXP_POS	151976	Applied PEEP	Positive end expiratory pressure applied to the airway.
16. PEEP	1	MDC_VENT_PRESS_AWAY_END_EXP_POS_S ETTING	1692919 2	Set PEEP	Positive end expiratory pressure applied to the airway by the ventilator during expiratory phase.
17. Apnea	1	MDC_TIME_PD_APNEA	151856	Apnea Duration	Duration of apnea - no flow measured
17. Apnea	1	MDC_TIME_PD_APNEA_SETTING	1692907 2	Apnea alarm duration setting	
18. Patient Vent Sychroniza tion	1	MDC_VENT_PRESS_TRIG_SENS	152428	Ventilator pressure trigger sensitivity	Sensitivity of trigger in ventilator; a pressure value, for triggering an inflation.

IEEE Category	CMI Stat us	REFID	CF_COD E10	Common Term	Term Description
18. Patient Vent Sychroniza tion	1	MDC_VENT_PRESS_TRIG_SENS_SETTING	1692964 4		
18. Patient Vent Sychroniza tion	1	MDC_VENT_FLOW_TRIG_SENS	152804	Ventilator flow trigger sensitivity	Sensitivity of trigger in ventilator; a flow value, for triggering an inflation.
18. Patient Vent Sychroniza tion	1	MDC_VENT_FLOW_TRIG_SENS	1693002 0		
23. Miscellane ous	1	MDC_RESP_RAPID_SHALLOW_BREATHING_ INDEX	152860	Rapid Shallow Breathing Index	The rapid shallow breathing index (RSBI) is calculated by dividing the spontaneous breath rate by the tidal volume, averaged over one minute.
24. Ventilator Mode	1	MDC_VENT_MODE	184352	Ventilation mode	Selected mode of ventilator
24. Ventilator Mode	1	MDC_VENT_MODE_BACKUP	184400	Backup ventilation mode	Selected backup mode of ventilator
26. Gas Conc. and Partial Press	1	MDC_CONC_AWAY_CO2_ET	151708	End tidal carbon dioxide concentration (or partial pressure) in airway gas	Partial pressure of carbon dioxide in airway gas measured at the end of expiration
26. Gas Conc. and Partial Press	1	MDC_CONC_AWAY_CO2_EXP	151712	Expired carbon dioxide concentration (or partial pressure) in airway gas	Partial pressure of carbon dioxide in airway gas measured during expiration
26. Gas Conc. and Partial Press	1	MDC_CONC_GASDLV_CO2_EXP	153024	Concentration airway carbon dioxide expiratory (gas delivery system)	Concentration of carbon dioxide in airway gas measured during expiration in the system conducting gas from the patient
26. Gas Conc. and Partial Press	1	MDC_CONC_AWAY_02_ET	152440	End tidal oxygen concentration (or partial pressure) in airway gas	Partial pressure of oxygen in airway gas measured at the end of expiration

IEEE Category	CMI Stat us	REFID	CF_COD E10	Common Term	Term Description
26. Gas Conc. and Partial Press	1	MDC_CONC_AWAY_O2_EXP	153132	Expired oxygen concentration (or partial pressure) in airway gas	Partial pressure of oxygen in airway gas measured during expiration
26. Gas Conc. and Partial Press	1	MDC_CONC_AWAY_02_INSP	152196	Inspiratory oxygen concentration (or partial pressure) in airway gas	Partial pressure of oxygen in airway gas measured during inspiration
26. Gas Conc. and Partial Press	1	MDC_CONC_GASDLV_02_INSP_SETTING	1693036 0		

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