

The Center for Medical Interoperability Document Terms and Definitions

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Document Status Sheet

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 in specification format 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.
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1 Scope

1.1 Introduction and Purpose

This document establishes Terms and Definitions for use within The Center's efforts and documents. The principal intended reader of this document is expected to have a basic understanding of clinical informatics.

1.2 Requirements

This is normative document specifies terms and definitions that will be normatively or informatively referenced by other documents. As such, this document, in itself does not specify requirements.

2 References

2.1 Normative References

This document uses the following informative references.

[HL7-FHIR-RD]"FHIR Resource Device - Detailed Descriptions"
https://www.hl7.org/fhir/device-definitions.html[IHE-PCD-TF-G]:IHE Technical Frameworks Appendix D: Glossary"
http://ihe.net/uploadedFiles/Documents/Templates/IHE TF GenIntro Ap
pD Glossary Rev1.0 2014-07-01.pdf[IEEE-11073]"CEN ISO/IEEE 11073 Health informatics - Medical / health device
communication standards"
https://standards.ieee.org/downloads.html[NIST-SP]NIST Special Publications

https://csrc.nist.gov/publications/sp

2.2 Reference Acquisition

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Health Level Seven International (HL7), 3300 Washtenaw Avenue, Suite 227, Ann Arbor, MI 48104, US; Phone: +1 (734) 677-7777; <u>http://www.hl7.org/</u>

Integrating the Healthcare Enterprise (IHE), 820 Jorie Blvd, Oak Brook, IL 60523-2251 USA; Phone: +1 630-481-1004; <u>https://www.ihe.net/</u>

Institute of Electrical and Electronics Engineers (IEEE), 3 Park Avenue, 17th Floor, New York, NY 10016-5997; <u>http://www.ieee.org/</u>

3 Terms and Definitions

This document specifies terms and definitions for use in other documents.

4 Abbreviations and acronyms

This document uses the following abbreviations:

СМІ	Center For Medical Interoperability

IHE PCD	Integrating the Healthcare Enterprise Patient Care Device
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5 Overview

This document is the result of reviews involving a number of existing standards to leverage existing "Terms and Definitions" and, of those, which are (a) the most suitable for The Center's purposes; (b) have the best coverage for the relevant domain at hand; (c) are current and active. The conclusion was to use the following order for providing a definition for a Term or Definition:

Priority	Reference
FHIR	[HL7-FHIR-RD]
IEEE	Error! Reference source n ot found.
IHE	[IHE-PCD-TF-G]
The Center	This document

Table 1 Priority of Terms and Definitions References

In addition, security-related terms used in CMI documents are taken from [NIST-SP]. The summary of the specified terms and definitions are below, in Table 2. Note that the second column in Table 2.

provides references to the original source, when they exist. If no references are provided, then the definition was created by use within The Center's efforts.

Term	References	Definition	Notes and examples	
Device, Gateway, Platform Terms				
Aggregator		A computer system that performs aggregation of data from source medical devices. An Aggregator is typically delivered as an appliance, serves one bedside, forwards data to a Gateway or Platform. Bernoulli, Capsule/Qualcomm, etc provide aggregators.		
Client		Generic term that can refer to either a Device or a Gateway that communicates with a Platform		
Medical Interoperability Platform, or Platform		A computer system that complies with the Center's clinical data interoperability interface requirements to communicate with clients. It may also have other elements, such as data stores and APIs for applications such as electronic medical record systems, clinical decision support systems etc.		
Device	[HL7-FHIR-RD]	An instance or a type of a manufactured item that is used in the provision of healthcare without being substantially changed through that activity. The Device may be a medical or non-medical device. In CMI documents, the word Device usually refers to an Interoperable Medical Device as defined herein. Devices can be delivered as either software- only or a combination of software and hardware. Gateways and Platforms are Devices.		
Gateway		A Gateway is a computer system delivered as either a software application or hardware appliance which connects one or more Devices to another machine, application or Gateway. A Gateway typically provides one or more of the following functions: Aggregation, Forwarding, Translation, Accumulation. A Gateway typically serves multiple bedsides, typically forwards data to a Platform (Such as a CMI Platform) or a clinical IT application such as an EMR. A Gateway is typically provided by a device vendor to support that vendor's proprietary protocols (e.g. Draeger, Philips, GE, B Braun, etc. provide gateways)		
Interoperable Device		A Device which has the capability of electronically transmitting or receiving commands, measurements, settings, alarms, or any other type of information. An		

Term	References	Definition	Notes and examples
		Interoperable Device can also meet the definition of a Gateway if it has Gateway functionality.	
Medical Device	[HL7-FHIR-RD]	Medical Devices include durable (reusable) medical equipment, implantable devices, as well as disposable equipment used for diagnostic, treatment, and research for healthcare and public health. Unless the phrase "Non- medical Device" is used, the term "Device" can generally be understood as "Medical Device" in The Center's documents.	
Non-medical Device	[HL7-FHIR-RD]	Non-medical Devices include items such as a machine, cellphone, computer, application, printer etc.	
Personal Health Device		A Device that is owned or maintained by the patient, including a scale, blood pressure measurement Device, a glucometer, an activity monitor, etc.	
Point Of Care Device		A Device used in a patient care setting such as a hospital, clinic or, if not owned or maintained by the patient, in the home.	
Computing Terms			
Alerts		A warning or notification delivered to a user asynchronously to call the user's attention to an important or urgent clinical or equipment situation.	
Cache-And-Transfer		To Cache means to queue or accumulate data in such a way as to preserve its proper sequence. Cache-And-Transfer means the ability to Cache data when it cannot be transferred, and to transfer it once the ability to transfer is restored, in proper sequence.	
Configuration		The ability to alter, or the manner by which is altered, the behavior of a Device, Gateway, or Platform without modifying its software. Configuration can be performed via a user interface, configuration files, or other similar approach.	
Data Source		A Device or Gateway which provides clinical data to another Device, Gateway, or Platform.	
Notification		An asynchronous message or alert conveying an error or other unexpected condition	
Provision		To configure or otherwise set up a Device or Gateway so that it can be handed off to an end-user and/or made ready for use.	

Term	References	Definition	Notes and examples
Resource		A physical or virtual asset that can be used to perform a function	
Service		A Service is a software module which consists of an interface, a contract, and an implementation, to achieve a particular computing task. There is a service provider and a service consumer. The interface defines how the provider will process the requests from the consumer, the contract defines the specific data and protocol interaction between the provider and consumer, and the implementation is the actual software code for the service.	
Service Discovery		The automatic detection of devices and the services they offer on a computer network. This is achieved through Service Discovery Network Protocol(s).	
Software		Firmware, drivers, operating system, and application program components necessary for a Device or Gateway to perform its intended functions.	
Clinical Informatics T	erms		
Care Team Member		A clinician or caregiver who is part of the team of persons caring for a patient. For example the patient's doctor and nurse are members of the patient's care team.	
Vitals		Clinical measurements meant to measure the body's vital or essential functions, including Heart Rate, Blood Pressure, Temperature, Oxygen Saturation, Respiration.	
Waveform		The shape and form of a signal over time, usually sampled at more than 1 Hz. An electrocardiogram, a cardiorespirogram are examples of waveforms.	
Spot Check		Asynchronous acquisition of Vitals and other measurements	
Monitoring		Synchronous acquisition of Vitals and other measurements	
Security and Certificat	tes		
Audit (Noun)		The result of Auditing.	
Audit (Verb)	NIST SP 800-32	Independent review and examination of records and activities to assess the adequacy of system controls, to ensure compliance with established policies and operational procedures, and to recommend necessary changes in controls, policies, or procedures.	6

Term	References	Definition	Notes and examples
Authenticate	NIST SP 800-32	To confirm the identity of an entity when that identity is presented.	
Authentication	NIST SP 800-53; SP 800-53A; SP 800-27; FIPS 200; SP 800-30	Verifying the identity of a user, process, or Device, often as a prerequisite to allowing access to resources in an information system	For example for user authentication, this is typically accomplished by having the user provide credentials or authentication factors. For a Device or Gateway, this is typically accomplished using a signed certificate.
Authorization		Granting access to a resource or asset (such as a Device, application, process, or data) usually after authentication and according to a policy.	
Availability	NIST SP 800-53; SP 800-53A; SP 800-18; SP 800- 27; SP 800-37; SP 800-60; FIPS 200; FIPS 199; 44 U.S.C., Sec. 3542	Principle that authorized subjects are granted timely access to objects with sufficient bandwidth to perform the desired interaction.	
Certificate	NIST SP 800-32	A message that, at least, states a name or identifies the CA, identifies the Subscriber, contains the Subscriber's public key, identifies the Certificate's Validity Period, contains a Certificate serial number, and is digitally signed by the CA that issued the certificate.	
Certificate Policy (CP)	CNSSI-4009; NIST SP 800-32	A specialized form of administrative policy tuned to electronic transactions performed during certificate management. A Certificate Policy addresses all aspects associated with the generation, production, distribution, accounting, compromise recovery, and administration of digital certificates. Indirectly, a certificate policy can also govern the transactions conducted using a communications system protected by a certificate-based security system. By controlling critical certificate extensions, such policies and associated enforcement technology can support provision	
Certificate Revocation List (CRL)		A periodically (or exigently) issued list, digitally signed by a CA, of identified Certificates that have been revoked prior to their expiration dates. The list generally indicates the CRL issuer's name, the date of issue, the date of the next	

Term	References	Definition	Notes and examples
		scheduled CRL issue, the revoked Certificates' serial	
		numbers, and the specific times and reasons for revocation.	
Certificate Signing		A message conveying a request to have a Certificate issued.	
Request (CSR)			
Certification Authority		An entity authorized to issue, manage, revoke, and renew	
(CA)		Certificates in the PKI.	
Confidentiality	NIST SP 800-53;	Preserving authorized restrictions on information access	
	SP 800-53A; SP 800-18; SP 800-	and disclosure, including means for protecting personal privacy and proprietary information.	
	27; SP 800-60;	privacy and proprietary mormation.	
	SP 800-37; FIPS		
	200; FIPS 199;		
	44 U.S.C., Sec.		
	3542		
Cryptographic		Methods, tools, and techniques pertaining to Cryptography.	
Cryptography	NIST SP 800-59	The discipline that embodies the principles, means, and	
		methods for the transformation of data in order to hide	
		their semantic content, prevent their unauthorized use, or	
		prevent their undetected modification.	
Data Integrity	NIST SP 800-27	The property that data has not been altered in an	
		unauthorized manner. Data integrity covers data in	
		storage, during processing, and while in transit.	
Device Certificate		An end-entity non-CA certificate of the PKI chain installed	
		in CMI Devices such as SAS Provider, Domain Proxy,	
		Installer, PAL and CBSD Devices.	
Digital Signature	NIST SP 800-63	An asymmetric key operation where the private key is used	
		to digitally sign data and the public key is used to verify the	
		signature. Digital signatures provide authenticity	
		protection, integrity protection, and non-repudiation.	
Elliptic Curve		A public-key cryptography system based on the algebraic	
Cryptography (ECC)		structure of elliptic curves over finite fields.	
Encryption		The process of changing plaintext into ciphertext through	
		use of an encryption algorithm to provide security and	
		privacy.	
Encryption Algorithm	CNSSI-4009	Set of mathematically expressed rules for rendering data	
		unintelligible by executing a series of conversions	
		controlled by a key.	

Term	References	Definition	Notes and examples
Extensible Authentication Protocol (EAP)	IETF RFC 3748	An authentication framework which supports multiple authentication methods. EAP typically runs directly over data link layers such as Point-to-Point Protocol (PPP) or IEEE 802, without requiring IP.	
Harm	ISO/IEC 51:1999, definition 3.3	Physical injury or damage to the health of people, or damage to property or the environment	
Hash		The output of a Hash Function	
Hash Function	NIST SP 800-63, FIPS 201	A function that maps a bit string of arbitrary length to a fixed length bit string. Robust hash functions satisfy the following properties: 1) One-Way. It is computationally infeasible to find any input that maps to any prespecified output. 2) Collision Resistant. It is computationally infeasible to find any two distinct inputs that map to the same output.	
Health System Certificate		A Digital Certificate used for a Health System	
Integrity		The property that information, Devices, or communications have not been improperly modified or destroyed, including ensuring information non-repudiation and authenticity.	This definition extends on scope included in NIST to include all aspects of interest to CMI.
Identity		The set of characteristics, including PKI certificates, network addresses, and user accounts (user ID and password) by which an individual, Device or Gateway is uniquely recognizable.	
Managed Digital Certificates Authority		An entity which controls and secures the assignment and revocation of Digital Certificates	
Message Integrity		Verification that received messages between communicating parties are authentic, that is what was sent by the sender is what is received by the recipient. Often achieved using a message authentication code (MAC).	
Non-repudiation	CNSSI-4009 and NIST SP 800-60	Assurance that the sender of information is provided with proof of delivery and the recipient is provided with proof of the sender's identity, so neither can later deny having processed the information.	

Term	References	Definition	Notes and examples
PKI Trust Anchor	NIST SP 800-57 Part 1	A public key and the name of a certification authority that is used to validate the first certificate in a sequence of certificates.	
Privacy		Ensuring access to communications or data is restricted only to authorized parties in accordance with federal laws and institutional (such as a care provider) policies.	
Private Key	NIST SP 800-57 Part 1	A cryptographic key, used with a public key cryptographic algorithm, that is uniquely associated with an entity and is not made public. In an asymmetric (public) cryptosystem, the private key is associated with a public key. Depending on the algorithm, the private key may be used, for example, to: 1) Compute the corresponding public key, 2) Compute a digital signature that may be verified by the corresponding public key, 3) Decrypt keys that were encrypted by the corresponding public key, or 4) Compute a shared secret during a key-agreement transaction.	
Public Key	NIST SP 800-57 Part 1	A cryptographic key, used with a public key cryptographic algorithm, that is uniquely associated with an entity and may be made public. In an asymmetric (public) cryptosystem, the public key is associated with a private key. The public key may be known by anyone.	
Public Key Infrastructure (PKI)		The architecture, organization, techniques, practices, and procedures that collectively support the implementation and operation of a Certificate-based public key cryptographic system.	
RSA		A public key cryptographic system (algorithm) invented by Rivest, Shamir, and Adelman.	
Secure Connection		A type of Device or Gateway connection which has enabled certain minimum security attributes such as encryption and authentication.	
Secure Software Download		A mechanism used to safely deploy new software to a managed Device and attest the authenticity of the Software. Safely in this context means that the downloaded Software is cryptographically signed and attestable by the Device being updated.	
Secure Software Update		A mechanism used to securely determine if a managed Device's Software needs to be updated, the subsequent secure Software download if an update is required, and the	

Term	References	Definition	Notes and examples
		further subsequent safe execution of the downloaded Software.	
Secure Transport		The digital transport of data performed in a secure manner, to include encryption, endpoint authentication, and data integrity	
Security Log		A data set whose purpose is to aid in the analysis of a security breach or other abnormal or illegal event by providing evidence or clues relating to that event.	
Threat	SP 800-53; SP 800-53A; SP 800-27; SP 800- 60; SP 800-37; CNSSI-4009	Any circumstance or event with the potential to adversely impact organizational operations (including mission, functions, image, or reputation), organizational assets, individuals, or other organizations through an information system via unauthorized access, destruction, disclosure, modification of information, and/or denial of service.	
Threat source	NIST FIPS 200; SP 800-53; SP 800-53A; SP 800-37	Intent and method targeted at the intentional exploitation of a vulnerability or a situation and method that may accidentally trigger a vulnerability.	
Transport Layer Security (TLS)	IETF RFC 5246	Provides communication security over the Internet. The protocol allows client/server applications to communicate in a way that is designed to prevent eavesdropping, tampering, or message forgery.	
Trust		A decision to believe and rely on the identity of a Device or individual that becomes the foundation for all other security controls and activities.	
Trust Anchor		A root of trust on which security decisions are made. In the context of the CMI, the Trust Anchor is the root certificate to which all other certificates chain.	
Trusted Device		A Device for which Trust has been established.	
Trusted Infrastructure		A computing infrastructure for which Trust has been established.	
Trusted Wireless Health		Wireless data transmission infrastructure used for healthcare for which Trust has been established.	
Vulnerability	NIST SP 800-53; SP 800-53A; SP 800-37; SP 800-	Weakness in an information system, system security procedures, internal controls, or implementation that could be exploited or triggered by a threat source.	

Term	References	Definition	Notes and examples
	60; SP 800-115; FIPS 200		
Zero-touch protocols		Networking protocols used to achieve zero-touch provisioning, which allows the secure insertion of a Device onto a network without manual intervention	
Types of Devices			L
Diagnostic		A Device which is used to gather information to form a diagnosis and can transmit Text, Image, Video, raw waveform, and/or structured data	Pulmonary Function, GI Endoscopy, ENT endoscopy, Vestibular Function, EKG, Evoked Response, Plethysmograph, Trans- esophageal Echo, etc
Hybrid		A Device that is a combination of other Devices	
Imaging		A Device that captures images and/or archives and/or communicates images	A PACS system, a medical wound imaging system
Locating		A Device that captures geographic location	An RTLS device for tracking providers, equipment, or patients
Modular		A Device that has optional modules	
Monitoring		A Device, including Primitive Devices, which acquires information from a patient and transmits this either continuously or intermittently	ICU monitor, EEG monitor, Smart Bed, Capnography, Cardiac Output
Primitive		An interoperable Device which is merely capable of transmitting an unsolicited data packet every few seconds/minutes	Simple pulse oximetry or non-invasive blood pressure device
Sensor		A probe or other measurement Device that touches or is wearable on a patient's body includes some means to communicate the measurements	Home weight scale, glucose measurement patch, ECG wearable sensor
Static		A Device that has no modularity	
Therapeutic		A Device that delivers something into a patient's body such as fluids, medication, oxygen	Patient-Controlled analgesia pump, IV pump, Ventilator

Term	References	Definition	Notes and examples
Device or Client Interoperability Attributes			<u> </u>
Accumulation		A Gateway Device function that involves persisting all or a subset of the data it receives or acquires, and makes the persisted data available for queries.	
Aggregation		A Gateway Device function that involves receiving data from one or more Devices.	
Can be controlled via interface		The interface support sending data to the Device which modifies its state	IV pump's rate might be changed, Ventilator's settings might be changed
Can be queried for historical data		The Device accumulates data which can be queried through the interface	A PACS system
Forwarding		A Gateway Device function that involves routing, filtering, and/or forwarding data from one or more other Devices	
Has an Interface		The Device can exchange information to and/or from another Device	Wired Networking interface, wireless networking interface, serial (RS-232, RS-422), parallel (IEEE 1284), USB, Bluetooth 2, Bluetooth 4, etc
Has a digital interface		The Device has an interface and the data exchanged is digital (as opposed to analog)	
Has network capability		The Device has Bluetooth, WiFi, Ethernet, or other TCP/IP network protocol support	
Mapping		A Gateway or Device function that involves mapping data it receives or acquires from one distinct data model into another	
Not interoperable		The Device is not an Interoperable Device	An electronic cuff pressure machine used at home that doesn't have an interface capability
Receive-only		The Device can only receive, but cannot send clinical data ¹ .	

¹ Clinical data as opposed to data that might be necessary as part of the device protocol. For example, an "ack" (acknowledgement) in response to the device transmitting clinical data is not clinical data

Term	References	Definition	Notes and examples
Supports communication standard(s)		The Device communicates using one or more standards	e.g. IHE PCD 01
Supports nomenclature standard(s)		The Device identifies clinical concepts using one or more standards	e.g. IEEE 11073.1001
Supports security standard(s)		The Device supports security related standards	e.g. TLS, XAML, OAuth, Hotspot 2.0
Transformation		A Gateway or Device that performs one or more of: Translation, Mapping, Filtering.	
Translation		A Gateway or Device function that involves translating data it receives or acquires from the form used by one system into the form required by another	
Transmit-only		The Device can only send, but cannot receive clinical data.	
Transmit/Receive		The Device can receive and send clinical data	
Transmits Continuously		The Device transmits at least once per minute	ICU monitor, telemetry
Transmits Episodically		The Device transmits data irregularly, in a clinical event- based fashion.	an electronic fall monitor transmits data when it detects a potential fall
Transmits Periodically		The Device transmits at most once per minute	A non-invasive blood pressure device can be set for 5 minutes but not every minute
Wired interface		The interface is through a physical port on the Device	Serial/parallel port, Ethernet, USB, etc
Wireless interface		The interface is wireless	WiFi, Bluetooth, etc
		Device Functional Attributes	<u></u>
Connects to the patient		The Device touches the patient continuously or intermittently in order to perform its function	
Clinician Controlled		The Device can be activated or set by a clinician	A ventilator is clinician controlled. A Patient Controlled Analgesia pump is clinician controlled.

Term	References	Definition	Notes and examples
Patient aware		The Device holds a patient identifier	
Patient Controlled		The Device can be activated or set by a patient	A home health scale is patient controlled. A Patient Controlled Analgesia pump is patient controlled.
User Aware		The Device has the notion of different users or user roles	
User Role Aware		The Device has the notion of user roles – for example a patient, clinician, biomedical engineer, administrator might be users.	

Table 2 Terms and Definitions

Appendix I. Acknowledgements

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