BSI Standards Publication

Health informatics — Device interoperability

Part 10700: Point-of-care medical device communication — Standard for base requirements for participants in a Service-oriented Device Connectivity (SDC) system

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The UK participation in its preparation was entrusted to Technical Committee IST/35, Health informatics.

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EUROPÄISCHE NORM

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Health informatics - Device interoperability - Part 10700: Point-of-care medical device communication - Standard for base requirements for participants in a Service-oriented Device Connectivity (SDC) system (ISO/IEEE 11073-10700:2024)

Informatique de santé - Interopérabilité des dispositifs - Partie 10700: Communication entre dispositifs médicaux sur le site des soins - Norme relative aux exigences de base pour les participants à un système de connectivité de dispositifs orientée services (SDC) (ISO/IEEE 11073-10700:2024)

Medizinische Informatik - Interoperabilität von Geräten - Teil 10700: Kommunikation persönlicher Gesundheitsgeräte - Standard für Basisanforderungen für Teilnehmer an einem serviceorientierten Gerätekonnektivitätssystem (SDC) (ISO/IEEE 11073-10700:2024)

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A list of all parts in the ISO 11073 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.**Abstract:** Medical devices that offer a communication interface as specified by the IEEE 11073 Service-oriented Device Connectivity (SDC) standards can be integrated into a health IT system to jointly execute system functions. However, implementing the IEEE 11073 SDC communication protocol is not sufficient to demonstrate safety, effectiveness, and security of system functions resulting from the combination of system function contributions from two or more medical devices. SDC participant key purposes (PKPs) are sets of requirements that allow for manufacturers to have certain expectations about BICEPS participants from other manufacturers. This common understanding enables the manufacturers to perform risk management, verification, validation, and usability engineering for the safe use of system functions. This standard specifies requirements for the allocation of responsibilities to SDC base participants.

Keywords: base PKP; BICEPS; communication protocol specification; documentation and process responsibilities; dynamic medical device interoperability; IEEE 11073-10700™; integrated clinical environment; participant key purpose; point-of-care medical device communication; risk management; SDC; service-oriented device connectivity; safety, effectiveness, and security; system function; system function contribution; usability engineering

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Introduction

This introduction is not part of IEEE Std 11073-10700-2022, Health Informatics—Device Interoperability—Part 10700: Point-of-Care Medical Device Communication—Standard for Base Requirements for Participants in a Service-Oriented Device Connectivity (SDC) System.

The IEEE 11073 Point-of-Care Medical Device Communication Standards enable communication between health IT elements in a HEALTH IT SYSTEM including MEDICAL DEVICEs. They provide automatic and detailed electronic data capture of patient vital signs information and device operational data. The primary goals are to:

— Provide real-time plug-and-play interoperability for MEDICAL DEVICEs. “Real-time” means that data from multiple MEDICAL DEVICEs can be retrieved, temporally correlated, displayed, and processed in fractions of a second. “Plug-and-play” means that there are no recurring configuration steps necessary to enable data exchange between MEDICAL DEVICEs.

— Facilitate the efficient and effective exchange of vital signs and MEDICAL DEVICE data acquired at the PoC in all health care environments. “Efficient and effective exchange of MEDICAL DEVICE data” means that data captured at the PoC, e.g., patient vital signs, can be received, parsed, and interpreted by different types of applications without the loss of safety-critical information.

The IEEE 11073 Point-of-Care Medical Device Communication Standards are targeted at surgical as well as acute and continuous care devices, such as patient monitors, ventilators, infusion pumps, ECG devices, endoscopic camera systems, insufflators, dissectors, etc. They build a family of standards that can be bound to one another to provide optimized connectivity for devices at the PoC.

Within the context of the ISO/IEEE 11073 family of standards for Point-of-Care Medical Device Communication, this standard defines the requirements for SDC BASE PARTICIPANTs in an SDC SYSTEM that comprises an IT NETWORK of MEDICAL DEVICEs to enable safe and secure contribution to SYSTEM FUNCTIONs.

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Health Informatics—Device Interoperability

Part 10700: Point-of-Care Medical Device Communication—Standard for Base Requirements for Participants in a Service-Oriented Device Connectivity (SDC) System

1. Overview

1.1 Scope

This standard specifies the base set of Participant Key Purposes (PKPs) for the Service-oriented Device Connectivity (SDC) series of standards. PKPs are role-based sets of requirements for products in order to support safe, effective, and secure interoperability in medical IT networks at point-of-care environments such as the intensive care unit (ICU), operating room (OR) or other acute care settings. This standard specifies both product development process and technical requirements.

1.2 Word usage

The word *shall* indicates mandatory requirements strictly to be followed in order to conform to the standard and from which no deviation is permitted (*shall* equals *is required to*).[6, 7]

The word *should* indicates that among several possibilities one is recommended as particularly suitable, without mentioning or excluding others; or that a certain course of action is preferred but not necessarily required (*should* equals *is recommended that*).

The word *may* is used to indicate a course of action permissible within the limits of the standard (*may* equals *is permitted to*).

The word *can* is used for statements of possibility and capability, whether material, physical, or causal (*can* equals *is able to*).

1.3 Service-oriented Device Connectivity standards

The SDC STANDARDs are a subset of the IEEE 11073 standards and define requirements for MEDICAL DEVICEs and other participants that exchange physiological or technical information or enable external control while being operated in an IT NETWORK.

The SDC STANDARDs comprise the specification of a domain and message model (IEEE Std 11073-10207) and transport technology (IEEE Std 11073-20702) that form a service-oriented MEDICAL DEVICE architecture (IEEE Std 11073-20701).[8] These SDC core standards constitute the technical building blocks for foundational, structural, and semantic MEDICAL DEVICE interoperability over secure data transmission. The SDC PKP STANDARDs (see 1.4) and particular SDC Device Specializations address additional levels.

1.4 Participant key purposes

MEDICAL DEVICEs that offer a communication interface as specified by the SDC STANDARDs can be integrated into a HEALTH IT SYSTEM on behalf of the SYSTEM OWNER, establishing an SDC SYSTEM to be used by the HEALTHCARE DELIVERY ORGANIZATION.

The SYSTEM FUNCTIONs made available in an SDC SYSTEM depend on the individual SYSTEM FUNCTION CONTRIBUTIONs of its BICEPS PARTICIPANTs. Accordingly, the MANUFACTURER of a BICEPS SERVICE

[6] The use of the word *must* is deprecated and cannot be used when stating mandatory requirements; *must* is used only to describe unavoidable situations.

[7] The use of *will* is deprecated and cannot be used when stating mandatory requirements; *will* is only used in statements of fact.

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PROVIDER can only specify its INTENDED SYSTEM FUNCTION CONTRIBUTIONs, whereas the MANUFACTURER of a BICEPS SERVICE CONSUMER can specify the intended SYSTEM FUNCTIONs as well as the SYSTEM FUNCTION CONTRIBUTIONs required from BICEPS SERVICE PROVIDERs in the SDC SYSTEM.

But to verify the safety, effectiveness, and security of these SYSTEM FUNCTIONs, only implementing the communication protocol based on the SDC STANDARDs is not sufficient. The safety, effectiveness, and security of the SDC SYSTEM is based on allocating responsibilities to the individual BICEPS PARTICIPANTs according to the requirements of the SDC PARTICIPANT KEY PURPOSEs (PKPs) they assume.

The responsibility for the individual products as BICEPS PARTICIPANTs in an SDC SYSTEM remains with the MANUFACTURERs whereas the SYSTEM OWNER is responsible for integration of the products into a HEALTH IT SYSTEM and the ADMINISTRATOR is responsible for operation and maintenance of the HEALTH IT SYSTEM (see ISO 81001-1:2021, Clause 4.5 [B16]).[9] In addition, the SYSTEM OWNER and ADMINISTRATOR take the responsibilities placed on them by declarations in the ACCOMPANYING INFORMATION of the individual products that are to be integrated, e.g., pertaining to configuration, NETWORK BANDWIDTH, etc.

The SDC PKP STANDARDs specify the allocation of responsibilities and allow for MANUFACTURERs to have certain expectations about BICEPS PARTICIPANTs from other MANUFACTURERs. Conformity to SDC PKP STANDARDs and indication of this conformity creates confidence in these expectations and enables MANUFACTURERs to take the responsibilities for SYSTEM FUNCTION CONTRIBUTIONs of their BICEPS PARTICIPANTs in an SDC SYSTEM. These responsibilities pertain to technical design, implementation, verification, validation, RISK MANAGEMENT, USABILITY ENGINEERING, and labeling of BICEPS PARTICIPANTs.

This standard defines the SDC BASE PROVIDER and the SDC BASE CONSUMER PKPs. They comprise the base requirements for MANUFACTURERs to support safe, effective, and secure operation of their SDC BASE PARTICIPANTs in an SDC SYSTEM.

MANUFACTURERs of SDC BASE PROVIDERs can assess and specify which requirements need to be fulfilled by SDC BASE CONSUMERs for the safe use of SYSTEM FUNCTION CONTRIBUTIONs. Based on conformity of SDC BASE CONSUMERs to this and other SDC PKP STANDARDs, SDC BASE PROVIDERs can restrict access to BICEPS SERVICEs in the HEALTH IT SYSTEM.

For exchanging metric data, ALERT information, and external control commands, conformity with further SDC PKP STANDARDs is recommended. Requirements that relate to specific SYSTEM FUNCTIONs or SYSTEM FUNCTION CONTRIBUTIONs can be specified in additional SDC PARTICIPANT KEY PURPOSEs.

2. Normative references

The following referenced documents are indispensable for the application of this document (i.e., they must be understood and used, so each referenced document is cited in text and its relationship to this document is explained). For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments or corrigenda) applies.

IEEE Std 11073-10101™, Health informatics—Point-of-care medical device communication—Part 10101: Nomenclature.[10, 11]

IEEE Std 11073-10207™, Health informatics—Point-of-care medical device communication—Part 10207: Domain Information and Service Model for Service-Oriented Point-of-Care Medical Device Communication.

IEEE Std 11073-20701™, Health informatics—Point-of-care medical device communication—Part 20701: Service-Oriented Medical Device Exchange Architecture and Protocol Binding.

[9] The numbers in brackets correspond to those of the bibliography in Annex D.

[10] The IEEE standards or products referred to in this annex are trademarks owned by The Institute of Electrical and Electronics Engineers, Incorporated.

[11] IEEE publications are available from The Institute of Electrical and Electronics Engineers (https://standards.ieee.org/).

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3. Definitions, acronyms, and abbreviations

3.1 Definitions

For the purposes of this document, the following terms and definitions apply. The *IEEE Standards Dictionary Online* should be consulted for terms not defined in this clause.[12]

ACCOMPANYING INFORMATION: Information accompanying or marked on a MEDICAL DEVICE or accessory for the USER or those accountable for the installation, use, processing, maintenance, decommissioning and disposal of the MEDICAL DEVICE or accessory, particularly regarding safe use. (adapted from ISO 20417:2021 [B14])

NOTE 1—The ACCOMPANYING INFORMATION is regarded as part of the MEDICAL DEVICE or accessory.[13]

NOTE 2—The ACCOMPANYING INFORMATION can consist of the label, marking, INSTRUCTIONS FOR USE, technical description, installation manual, quick reference guide, etc.

NOTE 3—ACCOMPANYING INFORMATION is not necessarily a written or printed document but could involve auditory, visual, or tactile materials and multiple media types (e.g., compact disc/digital video disc, USB stick, website).

NOTE 4—Definition has been modified by deleting Note 4 through Note 7.

ADMINISTRATOR: Legal person responsible for the ongoing operation of the implemented HEALTH IT SYSTEM and ensuring it is safeguarded and maintained on an ongoing basis. (adapted from ISO 81001-1:2021 [B16])

NOTE—Definition has been modified by replacing “person with role” with “legal person.”

ALERT: Generic term for physiological alarm conditions, technical alarm conditions, and conditions resulting in advisory signals. (adapted from IEC 60601-1-8:2006/AMD 2:2020 [B3])

NOTE—Definition has been modified by replacing “synonym for the combination of” with “generic term for” and “advisories” with “conditions resulting in advisory signals.”

BICEPS CONTAINMENT SUBTREE: A BICEPS CONTAINMENT TREE ENTRY and all child elements of that BICEPS CONTAINMENT TREE ENTRY, transitively including children of children etc. A BICEPS CONTAINMENT SUBTREE also includes all elements of any XML Schema type that extends pm:AbstractState that use @DescriptorHandle to refer to a node within the BICEPS CONTAINMENT SUBTREE as well as the element content, attributes, and child elements of these elements.

NOTE—This includes child elements of any XML Schema type that extends pm:AbstractDescriptor.

BICEPS CONTAINMENT TREE: Capability description and configuration state of a MEDICAL DEVICE SYSTEM. It constitutes a rooted tree of BICEPS CONTAINMENT TREE ENTRIEs, the hierarchy of which is specified in IEEE Std 11073-10207-2017, 5.3 [B10]. Its root node is a BICEPS CONTAINMENT TREE ENTRY of the XML Schema type pm:MdsDescriptor.

NOTE—There can be zero, one, or multiple BICEPS CONTAINMENT TREEs within a BICEPS SERVICE PROVIDER’s MDIB.

BICEPS CONTAINMENT TREE ENTRY: Single element of any XML Schema type that extends pm:AbstractDescriptor. It includes its element content, attributes, and those child elements that are not of any XML Schema type that extends pm:AbstractDescriptor. A BICEPS CONTAINMENT TREE ENTRY also includes all elements of any XML Schema type that extends pm:AbstractState that use @DescriptorHandle to refer to the node as well as all the element content, attributes, and child elements of these elements.

BICEPS PARTICIPANT: A network node that is part of a SOMDS and exchanges information by providing BICEPS SERVICEs, consuming BICEPS SERVICEs, or both.

[12] *IEEE Standards Dictionary Online* is available at: http://dictionary.ieee.org. An IEEE Account is required for access to the dictionary, and one can be created at no charge on the dictionary sign-in page.

[13] Notes in text, tables, and figures of a standard are given for information only and do not contain requirements needed to implement this standard.

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BICEPS SERVICE: Interface as specified in the IEEE 11073-10207 Service Model.

BICEPS SERVICE CONSUMER: BICEPS PARTICIPANT that consumes at least one BICEPS SERVICE.

BICEPS SERVICE PROVIDER: BICEPS PARTICIPANT that provides at least one BICEPS SERVICE.

CERTIFICATE: Electronic document that is digitally signed by a certification authority and that a participant in an IT NETWORK uses for proving its identity and authenticity.

NOTE—A common format for public key CERTIFICATEs is defined in ITU-T X.509 [B18].

CLINICAL FUNCTION: Function or feature intended to be used for one or more specific medical purposes including but not limited to examination, monitoring, or modification of the structure or function of an individual's body; prediction, prevention, diagnosis, prognosis, treatment, or alleviation of a medical condition.

CLINICAL USER: USER with clinical knowledge who is using a MEDICAL DEVICE in accordance with its intended medical purpose.

DISTINGUISHED NAME: Section in a CERTIFICATE that uniquely identifies and binds an entity to the authority that signed and issued the CERTIFICATE.

NOTE—ITU-T X.509 [B18] defines a minimum set of attributes for its DISTINGUISHED NAME.

EXCESSIVE LOAD CONDITION: IT NETWORK load that exceeds the MAXIMUM LOAD CONDITION.

EXTENDED KEY USAGE: Indication of one or more purposes for which the public key of a CERTIFICATE can be used.

NOTE—ITU-T X.509 [B18] specifies an EXTENDED KEY USAGE public key CERTIFICATE extension.

EXTENSION: An element that is a child of an ext:Extension element.

HEALTH IT SYSTEM: Combination of interacting health IT elements that is configured and implemented to support and enable a HEALTHCARE DELIVERY ORGANIZATION's specific health objectives. (adapted from ISO 81001-1:2021 [B16])

NOTE 1—Such elements include health software, MEDICAL DEVICEs, IT hardware, interfaces, data, procedures, and documentation.

NOTE 2—Definition has been modified by replacing "an individual or organization" with "a HEALTHCARE DELIVERY ORGANIZATION."

HEALTHCARE DELIVERY ORGANIZATION: Facility or enterprise such as a clinic or hospital that provides healthcare services. (ISO 81001-1:2021 [B16])

INSTRUCTIONS FOR USE: Portion of the ACCOMPANYING INFORMATION that is essential for the safe and effective use of a MEDICAL DEVICE or accessory directed to the USER of the MEDICAL DEVICE. (adapted from ISO 20417:2021 [B14])

NOTE 1—For the purposes of this document, instructions for the professional processing between uses of a MEDICAL DEVICE or accessory can be included in the INSTRUCTIONS FOR USE.

NOTE 2—The INSTRUCTIONS FOR USE, or portions thereof, can be located on the display of a MEDICAL DEVICE or accessory.

NOTE 3—MEDICAL DEVICEs or accessories that can be used safely and effectively without INSTRUCTIONS FOR USE are exempted from having INSTRUCTIONS FOR USE by some authorities having jurisdiction.

NOTE 4—Definition has been modified by deleting Note 1 and Note 5.

INTENDED SYSTEM FUNCTION CONTRIBUTION: Functional capability of a BICEPS PARTICIPANT that is intended by its MANUFACTURER to contribute to a SYSTEM FUNCTION.

NOTE—The actual SYSTEM FUNCTION CONTRIBUTION is determined when the BICEPS PARTICIPANT interoperates with a suitable counterpart and they execute a SYSTEM FUNCTION together.

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INTENDED USE: Use for which a MEDICAL DEVICE, process, or service is intended according to the specifications, instructions, and information provided by the MANUFACTURER. (ISO/IEC Guide 63:2019 [B17])

NOTE—The intended medical indication, patient population, part of the body or type of tissue interacted with, USER PROFILE, USE ENVIRONMENT, and operating principle are typical elements of the INTENDED USE.

IT NETWORK: System or systems composed of communicating nodes and transmission links to provide physically linked or wireless transmission between two or more specified communication nodes. (ISO 81001-1:2021 [B16])

LOCALIZATION SERVICE: A service interface that allows a BICEPS SERVICE CONSUMER to retrieve human-readable texts in different languages from a BICEPS SERVICE PROVIDER. (adapted from IEEE Std 11073-10207-2017 [B10])

NOTE—Definition has been modified by replacing “interface” with “service interface,” “SERVICE CONSUMER” with “BICEPS SERVICE CONSUMER,” and “translation table” with “BICEPS SERVICE PROVIDER.”

MANUFACTURER: Natural or legal person with responsibility for the design, manufacture, packaging, or labeling of medical electrical equipment, assembling a medical electrical system, or adapting medical electrical equipment or a medical electrical system, regardless of whether these operations are performed by that person or on that person’s behalf. (IEC 60601-1:2005/AMD 1:2012/AMD 2:2020 [B2])

MAXIMUM LOAD CONDITION: Maximum IT NETWORK load specified for an SDC BASE PARTICIPANT in NORMAL USE.

NOTE—MAXIMUM LOAD CONDITIONs can be derived from the minimum required network data rate specified, the maximum number of concurrent subscriptions, or the maximum rate of services being consumed, among others.

MEDICAL DEVICE: Instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the MANUFACTURER to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury
- Investigation, replacement, modification, or support of the anatomy or of a physiological process
- Supporting or sustaining life
- Control of conception
- Disinfection of MEDICAL DEVICEs
- Providing information by means of in vitro examination of specimens derived from the human body

and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which can be assisted in its intended function by such means. (ISO/IEC Guide 63:2019 [B17])

NOTE—Products which can be considered to be MEDICAL DEVICEs in some jurisdictions but not in others include:

- Disinfection substances
- Aids for persons with disabilities
- Devices incorporating animal and/or human tissues
- Devices for in-vitro fertilization or assisted reproductive technologies

MEDICAL DEVICE SYSTEM: Object-oriented abstraction of a device system comprising zero or more subsystems, all of which always operate within the same context, that provides information objects as defined in IEEE Std 11073-10207.

NOTE—Device systems or subsystems thereof are typically MEDICAL DEVICEs.

NETWORK BANDWIDTH: The maximum rate of data transfer across an IT NETWORK.

NORMAL USE: Operation, including routine inspection and adjustments by any USER, and stand-by, according to the INSTRUCTIONS FOR USE or in accordance with generally accepted practice for those MEDICAL DEVICEs provided without INSTRUCTIONS FOR USE. (IEC 62366-1:2015/AMD 1:2020 [B5])

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NOTE 1—NORMAL USE should not be confused with INTENDED USE. While both include the concept of use as intended by the MANUFACTURER, INTENDED USE focuses on the medical purpose while NORMAL USE incorporates not only the medical purpose, but maintenance, transport, etc. as well.

NOTE 2—USE ERROR can occur in normal use.

NOTE 3—MEDICAL DEVICEs that can be used safely without INSTRUCTIONS FOR USE are exempted from having INSTRUCTIONS FOR USE by some authorities with jurisdiction.

OBJECTIVE EVIDENCE: Data supporting the existence or verity of something. (IEC 60601-1:2005/AMD 1:2012/AMD 2:2020 [B2])

NOTE—OBJECTIVE EVIDENCE can be obtained through observation, measurement, testing, or other means.

REFERENCE IDENTIFIER: A unique, symbolic, and programmatic form of a nomenclature term. (adapted from IEEE Std 11073-10101-2019 [B9])

NOTE 1—The form is correlated to a context-free code, both of which are defined by the standards of the IEEE 11073 Nomenclature series.

NOTE 2—Definition has been modified by replacing “for the term” with “of a nomenclature term.”

REFERENCE SYSTEM: An SDC SYSTEM consisting of BICEPS PARTICIPANTs that complement one SDC BASE PARTICIPANT’s INTENDED SYSTEM FUNCTION CONTRIBUTIONs to emulate a realistic USE ENVIRONMENT.

NOTE 1—A REFERENCE SYSTEM is used to demonstrate an SDC BASE PARTICIPANT’s capability to execute SYSTEM FUNCTIONs together with other BICEPS PARTICIPANTs.

NOTE 2—A REFERENCE SYSTEM can be fully or partially simulated.

REMOVABLE SUBSYSTEM: A subsystem of a BICEPS SERVICE PROVIDER that can be attached to or removed from the BICEPS SERVICE PROVIDER and that is represented in the MDIB.

REPRESENTATIVE SDC PARTICIPANT: A BICEPS PARTICIPANT in a REFERENCE SYSTEM that either uses a SYSTEM FUNCTION CONTRIBUTION of an SDC BASE PROVIDER under test in order to provide a (simulated) SYSTEM FUNCTION of its own or provides one or more SYSTEM FUNCTION CONTRIBUTIONs that are required by an SDC BASE CONSUMER under test.

NOTE—A REPRESENTATIVE SDC PARTICIPANT can be an SDC BASE PARTICIPANT.

RESIDUAL RISK: RISK remaining after risk control measures have been implemented. (ISO/IEC Guide 63:2019 [B17])

RISK: Combination of the probability of occurrence of harm and the severity of that harm. (ISO 14971:2019 [B13])

RISK MANAGEMENT: Systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating, controlling, and monitoring RISK. (ISO/IEC Guide 63:2019 [B17])

SDC BASE CONSUMER: An SDC PARTICIPANT KEY PURPOSE that a BICEPS SERVICE CONSUMER can assume.

SDC BASE PARTICIPANT: BICEPS PARTICIPANT that assumes the SDC BASE CONSUMER PKP, SDC BASE PROVIDER PKP, or both.

SDC BASE PROVIDER: An SDC PARTICIPANT KEY PURPOSE that a BICEPS SERVICE PROVIDER can assume.

SDC PARTICIPANT ENSEMBLE: Logical system of SDC BASE PARTICIPANTs within an SDC SYSTEM that are intended to execute one or more SYSTEM FUNCTIONs together through their individual SYSTEM FUNCTION CONTRIBUTIONs.

NOTE 1—An SDC PARTICIPANT ENSEMBLE can be used to indicate a common context of SDC BASE PARTICIPANTs, which facilitates them to safely execute SYSTEM FUNCTIONs.

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