International Standard

ISO/IEEE 11073-10700

First edition
2024-09

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

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)

Reference number
ISO/IEEE 11073-10700:2024(en)

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Published in Switzerland

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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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PDF: ISBN 978-1-5044-9848-7 STD26263
Print: ISBN 978-1-5044-9849-4 STDPD26263

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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.

Acknowledgments

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ISO 20417:2021, Sections 3.2 and 3.11
ISO 81001-1:2021, Sections 3.2, 3.14, 3.1.12, 3.3.8, and 3.3.11
ISO 14971:2019, Section 3.18

Contents

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.

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

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.

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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.

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.

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])

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.

NOTE 2—Membership in an SDC PARTICIPANT ENSEMBLE expresses the intent to have the SDC BASE PARTICIPANT contribute to the joint execution of SYSTEM FUNCTIONs with other members.

NOTE 3—An SDC BASE PROVIDER is a member of an SDC PARTICIPANT ENSEMBLE for as long as the corresponding ensemble context state is associated and validated.

SDC PARTICIPANT KEY PURPOSE: A set of requirements that describes a role that a BICEPS PARTICIPANT can play in a SOMDS.

NOTE—The allocation of responsibilities according to SDC PARTICIPANT KEY PURPOSEs facilitates trust between BICEPS PARTICIPANTs.

SDC PKP STANDARD: Any SDC STANDARD that defines one or more SDC PARTICIPANT KEY PURPOSEs.

SDC STANDARD: IEEE 11073 parts 10207, 207xx, and 107xx (where "x" is a placeholder for a single digit), which cover Service-oriented Device Connectivity (SDC).

SDC SYSTEM: Part of a HEALTH IT SYSTEM that constitutes a SOMDS operated in an IT NETWORK.

SERVICE-ORIENTED MEDICAL DEVICE SYSTEM: Instance of a distributed system that implements a service-oriented architecture composed of BICEPS SERVICE PROVIDERs and BICEPS SERVICE CONSUMERs. (adapted from IEEE Std 11073-10207-2017 [B10])

NOTE—Definition has been modified by replacing "SERVICE PROVIDERs and SERVICE CONSUMERs as defined for IEEE Std 11073-10207" with "BICEPS SERVICE PROVIDERs and BICEPS SERVICE CONSUMERs."

SYSTEM FUNCTION: CLINICAL FUNCTION executed by two or more BICEPS PARTICIPANTs that are part of an SDC SYSTEM.

SYSTEM FUNCTION CONTRIBUTION: Function of a BICEPS PARTICIPANT that contributes to a SYSTEM FUNCTION.

SYSTEM FUNCTION USE SPECIFICATION: Section of the USE SPECIFICATION in accordance with IEC 62366-1 describing intended medical indication, intended patient population, intended part of the body or type of tissue applied to or interacted with, intended USER PROFILE, intended USE ENVIRONMENT, operating principle, and preconditions for the SYSTEM FUNCTIONs made available by an SDC BASE CONSUMER making use of SYSTEM FUNCTION CONTRIBUTIONs of SDC BASE PROVIDERs.

NOTE—SDC BASE PROVIDERs can declare limitations regarding BICEPS SERVICE CONSUMERs and their configuration for safe and effective use as specified in DR1034.

SYSTEM OWNER: Legal person accountable for ensuring the HEALTH IT SYSTEM being acquired and implemented will meet the HEALTHCARE DELIVERY ORGANIZATION's needs for its INTENDED USE. (adapted from ISO 81001-1:2021 [B16])

NOTE—Definition has been modified by replacing "senior executive" with "legal person" and "their organization's healthcare delivery services needs" with "the HEALTHCARE DELIVERY ORGANIZATION's needs."

USABILITY ENGINEERING: Application of knowledge about human behavior, abilities, limitations, and other characteristics to the design of MEDICAL DEVICEs (including software), systems and tasks to achieve adequate usability. (adapted from IEC 62366-1:2015/AMD 1:2020 [B5])

NOTE 1—Achieving adequate usability can result in acceptable RISK related to use.

NOTE 2—USABILITY ENGINEERING provides OBJECTIVE EVIDENCE that USERs can use a MEDICAL DEVICE safely and effectively, based on USER PROFILEs and the corresponding tasks and responsibilities USERs have in their daily work.

NOTE 3—USABILITY ENGINEERING is synonymous with human factors engineering.

NOTE 4—Definition has been modified by adding Note 2 and Note 3.

USE ENVIRONMENT: Actual conditions and setting in which USERs interact with the MEDICAL DEVICE. (IEC 62366-1:2015/AMD 1:2020 [B5])

NOTE—The conditions of use or attributes of the USE ENVIRONMENT can include hygienic requirements, frequency of use, location, lighting, noise, temperature, mobility, and degree of internationalization. Social attributes such as team versus individual, chaotic versus calm, stress level and length of shift can also play a role.

USE ERROR: USER action or lack of USER action while using the MEDICAL DEVICE that leads to a different result than that intended by the MANUFACTURER or expected by the USER. (IEC 62366-1:2015/AMD 1:2020 [B5])

USE SPECIFICATION: Summary of the important characteristics related to the context of use of the MEDICAL DEVICE. (adapted from IEC 62366-1:2015/AMD 1:2020 [B5])

NOTE 1—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 USE SPECIFICATION.

NOTE 2—Intended medical indication can include condition(s) or disease(s) to be screened, monitored, treated, diagnosed, or prevented.

NOTE 3—Patient population can include age group, weight range, health, or condition.

NOTE 4—The summary of the MEDICAL DEVICE USE SPECIFICATION is referred to by some authorities having jurisdiction as the ‘statement of intended use’.

NOTE 5—The USE SPECIFICATION is an input to determining the INTENDED USE of ISO 14971:2019 [B13].

NOTE 6—Definition has been modified by adding Note 2 and Note 3.

USER: Person interacting with (i.e., operating or handling) the MEDICAL DEVICE. (IEC 62366-1:2015/AMD 1:2020 [B5])

NOTE 1—There can be more than one USER of a MEDICAL DEVICE.

NOTE 2—Common USERs include clinicians, patients, cleaners, maintenance, and service personnel.

USER GROUP: Subset of USERs who are differentiated from other USERs by factors that are likely to influence their interactions with the MEDICAL DEVICE. (IEC 62366-1:2015/AMD 1:2020 [B5])

USER PROFILE: Summary of the mental, physical, and demographic traits of a USER GROUP, as well as characteristics, such as knowledge, skills, and abilities, which can have a bearing on design decisions. (IEC 62366-1:2015/AMD 1:2020 [B5])

3.2 Acronyms and abbreviations

ARP Address Resolution Protocol

ASN.1 Abstract Syntax Notation One

BICEPS Basic Integrated Clinical Environment Protocol Specification; non-normative name of IEEE Std 11073-10207-2017

DiffServ Differentiated Services

ECG Electrocardiography

EKU EXTENDED KEY USAGE

HDO HEALTHCARE DELIVERY ORGANIZATION

ICMP Internet Control Message Protocol

ICS Implementation Conformity Statement

IFU INSTRUCTIONS FOR USE

IP Internet Protocol

MDIB Medical Data Information Base

MDS MEDICAL DEVICE SYSTEM

NTP Network Time Protocol

OID Object Identifier

PKP Participant Key Purpose

PoC Point-of-Care

RefId REFERENCE IDENTIFIER

SDC Service-oriented Device Connectivity

SOMDS SERVICE-ORIENTED MEDICAL DEVICE SYSTEM

TCP Transmission Control Protocol

TLS Transport Layer Security

UDI Unique Device Identification

UDP User Datagram Protocol

UI User Interface

UTC Coordinated Universal Time

XML Extensible Markup Language [B23]

4. Notational conventions

Within this standard, the term *requirement* refers to

- Obligations (indicated by the keyword “SHALL”)
- Recommendations (indicated by the keyword “SHOULD”)
- Permissible courses of action (indicated by the keyword “MAY”)

4.1 Requirement categories and numbering

This standard assigns unique numbers to identify requirements. Every numbered requirement includes exactly one requirement level keyword. The numbers persist across the revisions of this document. A requirement number starts with an R followed by a zero-padded four-digit number. The resulting format is Rxxxx with xxxx being the padded number. Padding is expanded once the standard exceeds 9999 items.

The requirements in this standard are divided into two main sections: Responsibilities and Technical Design.

The Responsibilities section defines requirements towards processes and activities that are undertaken by a MANUFACTURER. These include RISK MANAGEMENT, USABILITY ENGINEERING, verification, validation, as well as postproduction activities. Throughout this document, Responsibilities requirements are prefixed with an additional R, i.e., RRxxxx. Conformity to these requirements can be assessed by review of the design history file or technical file. Conformity to requirements related to RISKs can be assessed by review of the risk management file. Use-related risk control measures are subject to the USABILITY ENGINEERING process. Their effectiveness as well as conformity to use-related requirements can be assessed by review of the usability engineering file.

If safety depends on contributing factors that are outside the MANUFACTURER's direct control, e.g., characteristics of the IT NETWORK, workflow organization, or employee training, the MANUFACTURER can delegate responsibilities to the HEALTHCARE DELIVERY ORGANIZATION, SYSTEM OWNER, and ADMINISTRATOR. For this purpose, the MANUFACTURER provides all necessary information and requires in the ACCOMPANYING INFORMATION that the specified actor assumes these responsibilities.

The Technical Design specifies technical requirements towards the implementation of SDC BASE PARTICIPANTs. Throughout this document, technical requirements are prefixed with a T, i.e., TRxxxx. Conformity to these requirements can be assessed by verification of the SDC BASE PARTICIPANT.

Both sections contain requirements towards the documentation of SDC BASE PARTICIPANTs, including the INSTRUCTIONS FOR USE and ACCOMPANYING INFORMATION. Documentation requirements are prefixed with a D, i.e., DRxxxx. Conformity to these requirements can be assessed by review of the documentation that is provided with an SDC BASE PARTICIPANT.

Each requirement number is uniquely assigned to a requirement text irrespective of its prefix. From outside this document, requirements can therefore be referenced using *IEEE 11073-10700-2022 Rxxxx* with xxxx being the requirement number.

4.2 References to IEEE 11073-10207 model elements

IEEE Std 11073-10207 defines the participant, message, and extension model as XML Schema**Error! Reference source not found.** Definitions [B25]. This specification references definitions from these models based on the following conventions:

- Every XML Schema attribute, element, or type is identified by a qualified name (see XML Namespaces**Error! Reference source not found.**, section 4 [B24]).
- Namespace prefixes of qualified names are used in accordance with BICEPS namespace prefix mappings (see IEEE Std 11073-10207).
- Nested XML element definitions or attribute definitions are separated from each other by using slashes ("/").
- Attributes are referenced by using the at-sign ("@").
- In order to express an attribute or element value to be one of a set of literals, this specification uses curly brackets enclosing the allowed literals separated by commas. "∈" denotes set membership.

4.2.1 Examples

- pm:Handle points to the XML type "Handle" defined in the participant model.
- msg:OperationInvokedReport/msg:ReportPart/@OperationTarget references an XML attribute named "OperationTarget." The attribute is defined in the XML element "ReportPart," which is defined in the XML element "OperationInvokedReport." The elements "ReportPart" and "OperationInvokedReport" both belong to the message model.
- pm:MetricQuality/@Mode ∈ { Test, Demo } expresses pm:MetricQuality/@Mode to be either Test or Demo.

4.3 XML Schema namespaces

Table 1 provides a mapping of the namespace prefixes that are used throughout this document to the IEEE 11073-10207 model parts.

Table 1—Mapping of namespace prefixes used in this standard

Namespace prefix	Model part
ext	IEEE 11073-10207] Extension model
pm	IEEE 11073-10207 Participant model
msg	IEEE 11073-10207 Message model

4.4 Notation of IEEE 11073 Nomenclature codes

To increase readability, all IEEE 11073 term code notations are listed as RefIds if applicable. Annex B shows all utilized RefIds and their translation to context-free IEEE 11073 Nomenclature codes.

5. Responsibilities

Requirements in this section primarily address the design and development of SDC BASE PARTICIPANTs.

Where this standard requires that a RISK is considered by a MANUFACTURER, that MANUFACTURER is responsible for the evaluation of that RISK, including its mitigation and the acceptance of the RESIDUAL RISK.

5.1 General responsibilities

RR1285: If there is potential for injury or death related to the use of an SDC BASE PARTICIPANT, the MANUFACTURER SHALL perform RISK MANAGEMENT and USABILITY ENGINEERING.

NOTE—This requirement can be fulfilled by applying recognized standards such as ISO 14971 [B12] and IEC 62366-1 [B4].

RR1006: When the MANUFACTURER of an SDC BASE PARTICIPANT discovers a deficiency in any SDC STANDARD, the MANUFACTURER SHALL provide information about the deficiency to the responsible IEEE Standards Committee or Working Group.

NOTE—IEEE SA contact information: https://standards.ieee.org/content/ieee-standards/en/about/contact/index.html

5.1.1 Post-market surveillance

RR1005: When the MANUFACTURER of an SDC BASE PARTICIPANT discovers deficiencies of another BICEPS PARTICIPANT, the MANUFACTURER SHALL provide information about the deficiency to the MANUFACTURER of the other BICEPS PARTICIPANT, unless the deficiency is already disclosed in the other BICEPS PARTICIPANT's list of non-conformities.

NOTE 1—Requirements, e.g., within the quality management system, of the MANUFACTURER can verify this.

NOTE 2—This does not constitute an obligation for the MANUFACTURER to systematically scrutinize other BICEPS PARTICIPANTs for such deficiencies.

5.1.2 Standard conformity

RR0024: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL demonstrate conformity of the SDC BASE PARTICIPANT to IEEE Std 11073-10207 except where superseded by normative statements in this standard.

RR0022: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL demonstrate conformity of the SDC BASE PARTICIPANT to the following requirements and subclauses of IEEE Std 11073-20701-2018 [B11] except where superseded by normative statements in this standard:

- **R0024 of 7.1 (Coded values)**
- **R0025, R0026, R0028, R0060, R0065 of 7.2.1 (Remote-control capabilities description)**
- **Subclause 7.2.2 (Remote-control capability behavior)**
- **Subclause 7.3 (Retrievability of containment tree entries)**
- **R0059 of 7.4 (Dynamic containment tree changes)**
- **Subclause 7.4.1 (Modular PoC Medical Devices)**
- **Subclause 7.5 (MDIB versioning)**
- **Subclause 7.6 (Types)**
- **R0056 of 8.1.1 (Subscription handling)**
- **Subclause 8.1.3 (Description event service)**
- **Subclause 8.1.4 (Localization service)**
- **Subclause 8.1.5 (Prioritization of connection establishment)**
- **Subclause 9.4.1 (Location context)**
- **R0044, R0045, R0063, R0064 of 10.1 (Cybersecurity)**
- **Subclause 10.2 (Patient safety)**

— **Subclause 10.3 (Clinical effectiveness)**

NOTE 1—A requirement or subclause is applicable to an SDC BASE PROVIDER if it has the subject “SDC PARTICIPANT” or “SDC SERVICE PROVIDER.” A requirement or subclause is applicable to an SDC BASE CONSUMER if it has the subject “SDC PARTICIPANT” or “SDC SERVICE CONSUMER.”

NOTE 2—IEEE Std 11073-20701-2018 [B11] also describes a BICEPS binding that this standard does not normatively reference. Whereas technical interoperability between BICEPS PARTICIPANTs requires a BICEPS binding, this standard does not prescribe a specific one.

5.1.2.1 Safety and essential performance standards

For some SYSTEM FUNCTIONs there are specific safety and essential performance requirements, including requirements regarding the UI, that originate from a standard for MEDICAL DEVICEs. Requirements from standards constitute the generally acknowledged state of the art and need to be considered by MANUFACTURERs of SDC BASE PARTICIPANTs that support related SYSTEM FUNCTIONs.

Whereas the MANUFACTURER of an SDC BASE PROVIDER is typically aware of such requirements, the MANUFACTURER of an SDC BASE CONSUMER needs to evaluate whether a standard becomes applicable by supporting a SYSTEM FUNCTION. But even if the SDC BASE CONSUMER is aware of an applicable standard, it cannot be aware of how the SDC BASE PROVIDER implements relevant requirements with regards to its SDC interface.

RR1919: For each INTENDED SYSTEM FUNCTION CONTRIBUTION of an SDC BASE PROVIDER, the MANUFACTURER of the SDC BASE PROVIDER SHALL evaluate which standards are applicable and demonstrate conformity of the SDC BASE PROVIDER to these standards.

RR1210: For each SYSTEM FUNCTION an SDC BASE CONSUMER is intended to execute, the MANUFACTURER of the SDC BASE CONSUMER SHALL evaluate which standards are applicable and demonstrate conformity of the SDC BASE CONSUMER to these standards.

NOTE 1—Particular standards (e.g., those from IEC 60601-2-x) can become applicable, e.g., because the SDC BASE CONSUMER displays metric information to a CLINICAL USER or allows for the invocation of external control operations that are subject to a particular standard.

NOTE 2—Conformity of the SDC BASE PROVIDER can be a prerequisite, see RR1920 and RR1213.

NOTE 3—Example: If an SDC BASE CONSUMER is intended to be used as an additional UI to a MEDICAL DEVICE that is subject to a particular standard, the SDC BASE CONSUMER will display metrics in accordance with that standard.

5.1.2.2 SDC PARTICIPANT KEY PURPOSE conformity

RR0028: For each SDC PARTICIPANT KEY PURPOSE indicated in the CERTIFICATE of an SDC BASE PARTICIPANT, the MANUFACTURER of the SDC BASE PARTICIPANT SHALL demonstrate conformity of the SDC BASE PARTICIPANT to the requirements of that SDC PARTICIPANT KEY PURPOSE.

RR1920: For those SYSTEM FUNCTIONs where an SDC BASE CONSUMER’s conformity to an applicable standard depends on an BICEPS SERVICE PROVIDER’s conformity to an SDC PARTICIPANT KEY PURPOSE, the MANUFACTURER of the SDC BASE CONSUMER SHALL consider the RISKs that result from executing SYSTEM FUNCTIONs with a BICEPS SERVICE PROVIDER that does not contain the required PKP OID in the EKU extension of its CERTIFICATE.

DR1930: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL provide in the ACCOMPANYING INFORMATION a list of SDC PARTICIPANT KEY PURPOSEs that the SDC BASE PARTICIPANT demonstrates conformity to.

NOTE—This supports the SYSTEM OWNER in verifying compatibility between SDC BASE PARTICIPANTs.

DR1932: For each SDC PARTICIPANT KEY PURPOSE an SDC BASE PARTICIPANT demonstrates conformity to, the MANUFACTURER of the SDC BASE PARTICIPANT SHALL provide in the ACCOMPANYING INFORMATION a list of all non-conformities, including for each non-conformity a rationale as to why it does not cause unacceptable RISKs during operation of an SDC SYSTEM.

5.1.2.3 Standards conformity of CONTAINMENT TREE ENTRIEs

For a SYSTEM FUNCTION to conform to a standard for MEDICAL DEVICEs, MANUFACTURERs or standards committees can derive sets of requirements specific to the SDC BASE PROVIDERs and the SDC BASE CONSUMERs that contribute to this SYSTEM FUNCTION. SDC BASE CONSUMERs need means to determine as to whether an SDC BASE PROVIDER conforms to such a set of requirements.

OIDs can be assigned to facilitate machine-readable references to these sets and an SDC BASE PROVIDER can disclose conformity of its INTENDED SYSTEM FUNCTION CONTRIBUTION to such a set of requirements and/or particular standard by using the pm:ProductionSpecification element.

A mechanism for conformity indication to a set of requirements and/or particular standard is defined in 6.2, TR0108.

RR0845: For each BICEPS CONTAINMENT TREE ENTRY of which the SDC BASE PROVIDER indicates conformity to a set of requirements, the MANUFACTURER of the SDC BASE PROVIDER SHALL demonstrate conformity of the parts represented by the BICEPS CONTAINMENT SUBTREE that has the BICEPS CONTAINMENT TREE ENTRY as its root to these requirements.

RR1213: For those SYSTEM FUNCTIONs where an SDC BASE CONSUMER's conformity to an applicable standard depends on an SDC BASE PROVIDER's fulfilment of a specific set of requirements, the MANUFACTURER of the SDC BASE CONSUMER SHALL consider the RISKs that result from using elements from BICEPS CONTAINMENT SUBTREEs where conformity to this set of requirements is not indicated.

DR1241: The MANUFACTURER of an SDC BASE PROVIDER SHALL provide in the ACCOMPANYING INFORMATION a list of OIDs that identify the sets of requirements the SDC BASE PROVIDER or a part of it indicates conformity to.

NOTE—This supports the SYSTEM OWNER in verifying compatibility between SDC BASE PARTICIPANTs.

DR0032: For each set of requirements an SDC BASE PROVIDER indicates conformity to, the MANUFACTURER of the SDC BASE PROVIDER SHALL provide in the ACCOMPANYING INFORMATION a list of all non-conformities, including for each non-conformity a rationale as to why it does not cause unacceptable RISKs during operation of an SDC SYSTEM.

5.2 Intended interoperability

SDC BASE PROVIDERs and SDC BASE CONSUMERs have different responsibilities when contributing to a SYSTEM FUNCTION.

An SDC BASE PROVIDER provides by means of the descriptive part of its MDIB all necessary information for an SDC BASE CONSUMER to assess the SDC BASE PROVIDER's potential SYSTEM FUNCTION CONTRIBUTIONs.

Before an SDC BASE CONSUMER consumes BICEPS SERVICEs that initiate the execution of a SYSTEM FUNCTION, the SDC BASE CONSUMER assesses the SDC BASE PROVIDER's potential SYSTEM FUNCTION CONTRIBUTIONs in order to determine whether through their individual contributions they can safely execute the SYSTEM FUNCTION together.

This implies the SDC BASE CONSUMER that initiates the execution of a SYSTEM FUNCTION needs to be able to interpret (on its own or through interaction with a USER) the MDIB of the SDC BASE PROVIDER.

The @SafetyClassification is a necessary attribute to consider when an SDC BASE CONSUMER assesses the suitability of an SDC BASE PROVIDER's potential SYSTEM FUNCTION CONTRIBUTION to a SYSTEM FUNCTION that the SDC BASE CONSUMER is intended to make available. However, the SDC BASE CONSUMER needs to evaluate additional characteristics of the SDC BASE PROVIDER's capabilities to determine the suitability, e.g., time-related attributes of a measurement.

Knowing the RISKs and clinical benefits of the SYSTEM FUNCTION, the MANUFACTURER of the SDC BASE CONSUMER can specify the characteristics required of the SDC BASE PROVIDER for safely executing the SYSTEM FUNCTION together.

The MANUFACTURER of the SDC BASE PROVIDER cannot be aware of every SYSTEM FUNCTION that the SDC BASE PROVIDER can contribute to. Therefore, the MANUFACTURER of the SDC BASE PROVIDER can only consider that part of the sequence of events that comprises the provision of its SYSTEM FUNCTION CONTRIBUTION.

For specific SYSTEM FUNCTION CONTRIBUTIONs, additional responsibilities can be specified in further SDC PKP STANDARDs, IEEE 11073 Device Specializations, or applicable particular standards.

DR0035: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL declare every INTENDED SYSTEM FUNCTION CONTRIBUTION of the SDC BASE PARTICIPANT in the ACCOMPANYING INFORMATION.

NOTE 1—The operating principle of the INTENDED SYSTEM FUNCTION CONTRIBUTION and the mapping of the INTENDED SYSTEM FUNCTION CONTRIBUTION to the capabilities represented by the MEDICAL DEVICE SYSTEM are typical elements of this declaration.

NOTE 2—This supports the SYSTEM OWNER in configuring the SDC BASE PARTICIPANTs to make SYSTEM FUNCTIONs available in the HEALTHCARE DELIVERY ORGANIZATION's SDC SYSTEM.

DR1032: The MANUFACTURER of an SDC BASE CONSUMER SHALL declare in the IFU every SYSTEM FUNCTION the SDC BASE CONSUMER is intended to execute along with every limitation concerning USER PROFILEs, USE ENVIRONMENTs, and medical indications.

NOTE 1—SDC BASE CONSUMERs do not only specify their own INTENDED SYSTEM FUNCTION CONTRIBUTIONs, but also the intended SYSTEM FUNCTIONs as a whole.

NOTE 2—Example of a limitation related to the USE ENVIRONMENT: The MANUFACTURER of an SDC BASE CONSUMER making data from an SDC BASE PROVIDER available to a USER declares in the IFU that it is only permitted to use the SDC BASE CONSUMER at locations where the SDC BASE PROVIDER is also visible to the USER.

NOTE 3—Example of a limitation related to the USER PROFILE: The MANUFACTURER of an SDC BASE CONSUMER being used by USER GROUPs with general medical knowledge declares in the IFU that using this SDC BASE CONSUMER for external control of SDC BASE PROVIDERs has to be limited to those USER GROUPs that are declared in the ACCOMPANYING INFORMATION of the SDC BASE PROVIDER.

DR1034: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL declare in the ACCOMPANYING INFORMATION all conditions required for safe use including constraints on the characteristics and/or configuration of other BICEPS PARTICIPANTs it communicates with on the IT NETWORK.

NOTE 1—Examples of such conditions:

- Constraints on the configuration of other BICEPS PARTICIPANTs in order to satisfy applicable particular or collateral standards, e.g., the configuration of display colors or units of measurement
- Limitation of access to SYSTEM FUNCTIONs to specific USER PROFILEs
- Constraints declared by an SDC BASE PROVIDER on BICEPS SERVICE CONSUMERs for executing an external control operation

NOTE 2—Some conditions can be relevant for the IFU, which is part of the ACCOMPANYING INFORMATION.

DR1166: If the conditions required for safe use of an SDC BASE PARTICIPANT include constraints on the characteristics and/or configuration of other BICEPS PARTICIPANTs it communicates with, the MANUFACTURER of the SDC BASE PARTICIPANT SHALL require in the ACCOMPANYING INFORMATION that the SYSTEM OWNER verifies conformity to these constraints.

NOTE—For example, the ACCOMPANYING INFORMATION requires of the SYSTEM OWNER

- To verify the correct configuration of an SDC BASE PROVIDER when bringing an SDC BASE CONSUMER into service,
- To verify the correct configuration of display colors or units of measurement of other BICEPS PARTICIPANTs, and
- To prevent changes of the configuration by unauthorized personnel.

RR1035: The MANUFACTURER of an SDC BASE PROVIDER SHALL consider the RISKs that result from executing SYSTEM FUNCTIONs with a BICEPS SERVICE CONSUMER that does not contain the SDC BASE CONSUMER PKP OID in the EKU extension of its CERTIFICATE.

NOTE 1—The use of CERTIFICATE EKU extensions is described in IEEE Std 11073-20701-2018, 10.2.3 (Trust establishment) [B11].

NOTE 2—The Base Consumer PKP OID is defined in A.2.2.

5.2.1 Types

IEEE Std 11073-10207-2017, B.187 [B10] introduces pm:CodedValue that allows for describing the semantic meaning of the element that contains it. IEEE Std 11073-20701-2018, 7.6 [B11] furthermore defines certain types as mandatory in order to facilitate interpretation of these elements. In addition to SDC BASE PROVIDERs, the following requirements also address SDC BASE CONSUMERs, which can use pm:CodedValue elements, e.g., in external control invocations.

RR1488: For each instance of pm:CodedValue of an SDC BASE PARTICIPANT, the MANUFACTURER of the SDC BASE PARTICIPANT SHALL verify that the concept identified by @Code correctly specifies the meaning of the element that contains the pm:CodedValue.

NOTE 1—The meaning of instances of pm:AbstractOperationDescriptor is specified by the combination of pm:Type and pm:OperationTarget, see IEEE Std 11073-20701-2018, R0025 in 7.2.1 [B11].

NOTE 2—The meaning specified by pm:Type can only be modified by an EXTENSION with @ext:MustUnderstand = true.

RR1817: For each instance of pm:CodedValue of an SDC BASE PARTICIPANT, the MANUFACTURER of the SDC BASE PARTICIPANT SHOULD verify that the coding system specified by @CodingSystem does not contain a code that is more specific in correctly defining the meaning of the element that contains the pm:CodedValue than the concept identified by @Code.

5.2.2 Sharing the clock object

In an SDC SYSTEM, each SDC BASE PARTICIPANT maintains an individual system clock. It cannot be ensured that the time provided by an SDC BASE PROVIDER is correct with regards to the actual point in time, but only that the same time source is used across different SDC BASE PARTICIPANTs, see IEEE Std 11073-20701-2018, 10.3.1 [B11].

RR1162: The MANUFACTURER of an SDC BASE CONSUMER SHALL consider the RISKs resulting from erroneous timestamps.

NOTE 1—If an SDC BASE CONSUMER uses timestamps to measure message delays, it can regularly compare clock information of an MDS with its own clock.

NOTE 2—The specific implementation depends on the time accuracy demands of the SDC BASE CONSUMER and clock details provided by the BICEPS SERVICE PROVIDER.

5.2.3 Sharing patient context information

RR1049: If an SDC BASE PARTICIPANT uses data from a pm:PatientContextState/pm:CoreData element for CLINICAL FUNCTIONs, the MANUFACTURER of the SDC BASE PARTICIPANT SHALL consider the RISKs resulting from incomplete, erroneous, or conflicting patient data.

NOTE 1—It is assumed that patient data can be incomplete, erroneous, or conflicting because a CLINICAL USER cannot be aware of all affected CLINICAL FUNCTIONs and RISKs when editing patient demographics in a hospital information system.

NOTE 2—Example of a RISK: The patient weight is used to compute displayed parameters; an erroneous weight leads to wrong values being displayed. Example of a mitigation: The patient weight is not automatically derived from patient core demographics; instead, a proposed value based on patient core demographics needs to be confirmed by the CLINICAL USER.

5.2.4 Sharing metric information

RR1067: The MANUFACTURER of the SDC BASE CONSUMER SHALL consider the RISKs that result from using received metric information.

NOTE 1—The preferred way of fulfilling this requirement is for the SDC BASE CONSUMER to conform to the Metric Consumer PKP defined in an additional, more specific SDC PKP STANDARD for metric provisioning.

NOTE 2—Examples of RISKs that result from using received metric information:

— Incomplete, erroneous, or delayed metric information is displayed to a CLINICAL USER, used in automated decision making processes, or provided to other systems supporting clinical decisions.

Examples of mitigations:

- The SDC BASE CONSUMER only uses metric information from SDC BASE PROVIDERs that conform to the Metric Provider PKP defined in an additional, more specific SDC PKP STANDARD for metric provisioning, to other applicable standards, or to other sets of requirements identified by an OID.
- The SDC BASE CONSUMER detects the loss, corruption, and delay of messages by technical means that are more comprehensively described in an SDC PKP STANDARD for metric provisioning.

NOTE 3—The risk assessment needs to address the foreseeable misuse that the CLINICAL USER relies on unreliable metric information.

5.2.5 Sharing alert information

RR1074: The MANUFACTURER of an SDC BASE CONSUMER SHALL consider the RISKs that result from using received ALERT system information, ALERT condition information, and ALERT signal information.

NOTE 1—The preferred way of fulfilling this requirement is for the SDC BASE CONSUMER to conform to the Alert Consumer PKP defined in an additional, more specific SDC PKP STANDARD for ALERT provisioning.

NOTE 2—Examples of RISKs that result from using received ALERT information or ALERT system information:

- Incomplete, erroneous, or delayed ALERT information or ALERT system information is used by a distributed ALERT system in which the CLINICAL USER does not need to stay within earshot of the participating BICEPS SERVICE PROVIDERs to observe the ALERT, or used for the remote display of an ALERT system state that the CLINICAL USER relies on.

Example of mitigations:

- The SDC BASE CONSUMER only uses ALERT information or ALERT system information from SDC BASE PROVIDERs that conform to the Alert Provider PKP defined in an additional, more specific SDC PKP STANDARD for ALERT provisioning, to other applicable standards, or to other sets of requirements identified by an OID.
- The SDC BASE CONSUMER detects the loss, corruption, and delay of messages by technical means that are more comprehensively described in an SDC PKP STANDARD for ALERT provisioning.

NOTE 3—The risk assessment needs to address the foreseeable misuse that the CLINICAL USER relies on unreliable ALERT information or ALERT system information.

5.3 System integration

DR1833: If an SDC BASE PARTICIPANT needs external resources to facilitate safe participation in an SDC SYSTEM, the MANUFACTURER of the SDC BASE PARTICIPANT SHALL require in the ACCOMPANYING INFORMATION that the SYSTEM OWNER and ADMINISTRATOR provide and maintain these resources.

NOTE 1—External resources include, but are not limited to, power supplies, (network) hardware, operating systems, virtualization environments, application platforms, and other software.

NOTE 2—This requirement allows for the deployment of software-only SDC BASE PARTICIPANTs in an SDC SYSTEM.

DR1168: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL disclose in the ACCOMPANYING INFORMATION all functional tests that the SYSTEM OWNER and the ADMINISTRATOR have to perform before a SYSTEM FUNCTION is executed for the first time or after major changes of the HEALTH IT SYSTEM.

NOTE 1—Such tests are intended, for example,

- To determine potential incompatibilities with other BICEPS PARTICIPANTs or elements of the HEALTH IT SYSTEM that have not been determined during product development and
- To verify correct installation and configuration in accordance with the ACCOMPANYING INFORMATION of the BICEPS PARTICIPANTs involved.

NOTE 2—Major changes include, but are not limited to:

- Changing the IT NETWORK configuration,
- Adding new elements to the HEALTH IT SYSTEM for the first time, and

— Upgrades or updates of elements of the HEALTH IT SYSTEM.

DR1595: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL declare in the ACCOMPANYING INFORMATION to which extent the HEALTHCARE DELIVERY ORGANIZATION is responsible for the management of instance identifiers.

NOTE 1—A HEALTHCARE DELIVERY ORGANIZATION typically maintains a master patient index (MPI) to assign and maintain unique patient identifiers, which can be used as primary patient identifiers in SDC.

NOTE 2—Additional indices are often maintained for HDO staff, which can be used, e.g., for operator context states, and internal locations, which can be used, e.g., for location context states.

5.3.1 Reference system

To help ensure a complete and consistent test approach for all SDC BASE PARTICIPANTs of an SDC SYSTEM, this standard defines requirements for test procedures. In addition to demonstrating conformity of an SDC BASE PARTICIPANT to IEEE Std 11073-10207 and applicable SDC PKP STANDARDs, a MANUFACTURER provides OBJECTIVE EVIDENCE that its SDC BASE PARTICIPANT can deliver its INTENDED SYSTEM FUNCTION CONTRIBUTIONs in a REFERENCE SYSTEM with other BICEPS PARTICIPANTs. To account for differences in the setup of the HEALTH IT SYSTEM operated by the HEALTHCARE DELIVERY ORGANIZATION, the responsibility for further tests is assigned to the SYSTEM OWNER before a SYSTEM FUNCTION is executed for the first time or after major changes of the HEALTH IT SYSTEM.

The REFERENCE SYSTEM test procedures described in this section are necessary to provide OBJECTIVE EVIDENCE that the SDC BASE PARTICIPANT is able to deliver its INTENDED SYSTEM FUNCTION CONTRIBUTIONs in a setting that simulates the intended operation by a HEALTHCARE DELIVERY ORGANIZATION. However, the REFERENCE SYSTEM tests are neither suitable nor sufficient to demonstrate conformity to the requirements of the SDC STANDARDs, including the SDC PKP STANDARDs.

RR1094: For each INTENDED SYSTEM FUNCTION CONTRIBUTION, the MANUFACTURER of an SDC BASE PROVIDER SHALL provide OBJECTIVE EVIDENCE that one or more SYSTEM FUNCTIONs that use the INTENDED SYSTEM FUNCTION CONTRIBUTION are available when being operated in a REFERENCE SYSTEM.

NOTE—OBJECTIVE EVIDENCE is obtained through one or more REFERENCE SYSTEM tests.

RR1655: For each SYSTEM FUNCTION an SDC BASE CONSUMER is intended to execute, the MANUFACTURER of the SDC BASE CONSUMER SHALL provide OBJECTIVE EVIDENCE that the SYSTEM FUNCTION is available when being operated in a REFERENCE SYSTEM.

NOTE—OBJECTIVE EVIDENCE is obtained through one or more REFERENCE SYSTEM tests.

RR1250: For each REFERENCE SYSTEM test required by an SDC PKP STANDARD, the MANUFACTURER of an SDC BASE PARTICIPANT SHALL verify that the REFERENCE SYSTEM is operated with every IT NETWORK configuration specified in the ACCOMPANYING INFORMATION of the SDC BASE PARTICIPANT under test.

RR1105: For each REFERENCE SYSTEM test required by an SDC PKP STANDARD, the MANUFACTURER of an SDC BASE PARTICIPANT SHALL verify that the REFERENCE SYSTEM is operated under every MAXIMUM LOAD CONDITION specified in the ACCOMPANYING INFORMATION of the SDC BASE PARTICIPANT under test.

RR1106: For each REFERENCE SYSTEM test required by an SDC PKP STANDARD, the MANUFACTURER of an SDC BASE PROVIDER SHALL verify that the REFERENCE SYSTEM is operated with the maximum number of REPRESENTATIVE SDC PARTICIPANTs communicating with the SDC BASE PROVIDER under test as specified in its ACCOMPANYING INFORMATION.

RR1098: For each REFERENCE SYSTEM test required by an SDC PKP STANDARD, the MANUFACTURER of an SDC BASE PARTICIPANT SHALL choose a REPRESENTATIVE SDC PARTICIPANT according to the following prioritization:

— **A production equivalent REPRESENTATIVE SDC PARTICIPANT that has been verified and validated.**

- **A prototyped REPRESENTATIVE SDC PARTICIPANT that has been developed to become a production equivalent and that is verified but not validated.**
- **A simulated REPRESENTATIVE SDC PARTICIPANT that has not been developed to become a production equivalent and that is verified but not validated.**

NOTE—A production equivalent REPRESENTATIVE SDC PARTICIPANT can be a released product or a test device that has been verified and validated.

DR1785: For each REFERENCE SYSTEM test required by an SDC PKP STANDARD, if the MANUFACTURER of an SDC BASE PARTICIPANT does not choose a production equivalent REPRESENTATIVE SDC PARTICIPANT that has been verified and validated, the MANUFACTURER SHALL provide a rationale for its choice.

RR1096: For each REFERENCE SYSTEM test required by an SDC PKP STANDARD, the MANUFACTURER of an SDC BASE PARTICIPANT SHOULD choose a REPRESENTATIVE SDC PARTICIPANT that is produced by a different MANUFACTURER than the SDC BASE PARTICIPANT under test.

RR1108: For each REFERENCE SYSTEM test required by an SDC PKP STANDARD, the MANUFACTURER of an SDC BASE PARTICIPANT SHOULD choose a REPRESENTATIVE SDC PARTICIPANT that runs a different SDC implementation than the SDC BASE PARTICIPANT under test.

NOTE—A different SDC implementation means that the SDC implementation of the REPRESENTATIVE SDC PARTICIPANT and the SDC BASE PARTICIPANT under test have been developed independently.

5.3.2 Characteristics of the IT NETWORK

DR1109: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL declare in the ACCOMPANYING INFORMATION the application protocols and transport protocols that need to be supported by the IT NETWORK and the communication endpoints that need to be accessible.

NOTE—Examples include:

- Application protocols: HTTP, TLS, NTP
- Transport protocols: TCP, UDP
- Communication endpoints: TCP/UDP ports

DR1110: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL declare in the ACCOMPANYING INFORMATION IP multicast requirements for the IT NETWORK.

DR1111: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL declare in the ACCOMPANYING INFORMATION that SYSTEM FUNCTIONs of other BICEPS PARTICIPANTs can be impaired by NETWORK BANDWIDTH consumption of the SDC BASE PARTICIPANT.

NOTE—For example, the MANUFACTURER provides instructions for the configuration of the IT NETWORK in order to deprioritize non-SDC traffic of the SDC BASE PARTICIPANT.

DR1587: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL declare the MAXIMUM LOAD CONDITIONs in the ACCOMPANYING INFORMATION.

DR0142: The MANUFACTURER of an SDC BASE PROVIDER SHALL declare in the ACCOMPANYING INFORMATION the maximum number of BICEPS SERVICE CONSUMERs that can concurrently communicate with the SDC BASE PROVIDER.

DR1113: The MANUFACTURER of an SDC BASE PROVIDER SHALL declare in the ACCOMPANYING INFORMATION:

- **the parameterization of QoS attributes,**
- **the required NETWORK BANDWIDTH under MAXIMUM LOAD CONDITIONs (outbound and inbound).**

NOTE 1—DR1113 pertains to non-SDC data traffic as well.

NOTE 2—QoS example: A MANUFACTURER declares the use of DiffServ to be parameterized with a certain per-hop behavior.

DR1116: The MANUFACTURER of an SDC BASE CONSUMER SHALL declare in the ACCOMPANYING INFORMATION the maximum acceptable latency of the IT NETWORK.

NOTE—The internal latency of a BICEPS SERVICE PROVIDER can be expressed by, e.g., pm:AbstractMetricDescriptor/@MaxDelayTime, pm:AlertConditionDescriptor/@DefaultConditionGenerationDelay, or pm:AbstractOperationDescriptor/@MaxTimeToFinish.

DR1117: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL declare in the ACCOMPANYING INFORMATION the required NETWORK BANDWIDTH (outbound and inbound).

RR1159: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL consider the RISKs that result from the SDC BASE PARTICIPANT's maximum consumed NETWORK BANDWIDTH under MAXIMUM LOAD CONDITIONs exceeding its required NETWORK BANDWIDTH as declared in the ACCOMPANYING INFORMATION.

NOTE—Example of mitigations: Declare in the ACCOMPANYING INFORMATION that the ADMINISTRATOR has to limit the NETWORK BANDWIDTH that is made available for the SDC BASE PARTICIPANT or that the SYSTEM OWNER has to provide an appropriately overprovisioned IT NETWORK.

DR1119: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL require in the ACCOMPANYING INFORMATION that the SYSTEM OWNER performs RISK MANAGEMENT for the HEALTH IT SYSTEM including the IT NETWORK.

NOTE—For example, it can require the application of RISK MANAGEMENT according to IEC 80001-1 [B6].

DR1122: The MANUFACTURER of an SDC BASE CONSUMER SHALL declare in the ACCOMPANYING INFORMATION hazardous situations resulting from communication failures of the IT NETWORK.

NOTE 1—The declaration of hazardous situations is intended to support the SYSTEM OWNER in planning mitigations for the event of an IT NETWORK failure.

NOTE 2—Examples of hazardous situations:

- Delayed clinical intervention resulting from the loss of an alarm distribution SYSTEM FUNCTION.
- Disruption in a clinical workflow resulting from the loss of a external control SYSTEM FUNCTION.

5.3.3 Excessive load conditions

RR0062: The MANUFACTURER of an SDC PARTICIPANT SHALL undertake all reasonable efforts to achieve that, while the SDC BASE PARTICIPANT is affected by EXCESSIVE LOAD CONDITIONs, the SDC BASE PARTICIPANT maintains its SYSTEM FUNCTION CONTRIBUTIONs for those BICEPS PARTICIPANTs that do not cause the EXCESSIVE LOAD CONDITIONs.

NOTE 1—EXCESSIVE LOAD CONDITIONs can result from

- Invoking external control commands at an excessive rate,
- Delivering state reports at an excessive rate, or
- Requesting the full MDIB at an excessive rate, among others.

NOTE 2—Reasonable efforts can be, for example,

- To prioritize the SDC BASE PARTICIPANT's resources to process the communication with those BICEPS PARTICIPANTs that do not cause the EXCESSIVE LOAD CONDITIONs
- To limit the SDC BASE PARTICIPANT's resources that are allocated to process the communication with those network nodes that cause the EXCESSIVE LOAD CONDITIONs

RR0148: The MANUFACTURER of an SDC BASE PROVIDER SHALL undertake all reasonable efforts to achieve that, while more BICEPS SERVICE CONSUMERs than specified in the ACCOMPANYING INFORMATION try to exchange secured messages with the SDC BASE PROVIDER in parallel, the SDC BASE PROVIDER maintains currently active SYSTEM FUNCTION CONTRIBUTIONs.

5.3.4 Failures of the IT NETWORK

5.3.4.1 Corruption of data

RR1170: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL consider the RISKs resulting from syntactically invalid SDC messages.

NOTE 1—If an SDC BASE PARTICIPANT cannot fully process received messages, it cannot clearly interpret the intent of the message.

NOTE 2—Examples:

- RISK: An SDC BASE CONSUMER cannot process a corrupted message from the BICEPS SERVICE PROVIDER and therefore does not detect that an ensemble context state of the BICEPS SERVICE PROVIDER has changed.
- Mitigation: The SDC BASE CONSUMER reconnects to the BICEPS SERVICE PROVIDER after receiving a corrupted message.

RR0129: For each INTENDED SYSTEM FUNCTION CONTRIBUTION, the MANUFACTURER of an SDC BASE PARTICIPANT SHALL consider the RISKs resulting from corruption of data.

NOTE 1—Whereas the integrity of SDC messages is protected by message authentication codes in TLS, corruption can still occur during processing within the SDC BASE PARTICIPANT.

NOTE 2—These are not novel RISKs introduced by distributed functionality but pertain to all MEDICAL DEVICEs that incorporate software. This requirement extends the general need for consideration to SYSTEM FUNCTION CONTRIBUTIONs in an SDC SYSTEM.

NOTE 3—Examples of RISKs:

- Due to a bit permutation in the target handle, the wrong operation target is selected.
- Due to a bit permutation in pm:CodedValue/@Code, a coded value is wrongly interpreted.

Examples of mitigations:

- An SDC BASE PROVIDER uses MDIB handles with a sufficiently large Hamming distance.
- An SDC BASE PROVIDER uses pm:CodedValue/@SymbolicCodeName to provide a redundant representation of the @Code for the SDC BASE CONSUMER to check against.

5.3.4.2 Delay and loss of communication

RR1297: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL consider the RISKs resulting from communication delay in the IT NETWORK.

NOTE—Example of a mitigation: The SDC BASE PARTICIPANT maintains those of its SYSTEM FUNCTION CONTRIBUTIONs that do not depend on the communication that is delayed.

RR1125: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL consider the RISKs resulting from loss of communication in the IT NETWORK.

NOTE 1—This does not affect the need for provision of evidence for the effective use of SYSTEM FUNCTIONs according to the SYSTEM FUNCTION USE SPECIFICATION.

NOTE 2—Examples of mitigations:

- The SDC BASE PARTICIPANT detects loss of communication in the IT NETWORK and notifies the CLINICAL USER.
- The IFU include instructions for how to mitigate RISKs in case of loss of communication in the IT NETWORK.
- The ACCOMPANYING INFORMATION of the SDC BASE PARTICIPANT requires of the SYSTEM OWNER to establish procedures that are appropriate to compensate loss of communication in the IT NETWORK.
- An SDC BASE PROVIDER providing external control operations allows for the USER to control these operations directly at the SDC BASE PROVIDER.
- An SDC BASE PROVIDER providing measurements allows for the USER to display these measurements directly at the SDC BASE PROVIDER.
- An SDC BASE CONSUMER does not support a SYSTEM FUNCTION the loss of which would cause an unacceptable RESIDUAL RISK.

NOTE 3—The following examples of mitigations can reduce RESIDUAL RISKs but are not deemed appropriate to mitigate unacceptable RISKs:

— The ACCOMPANYING INFORMATION of the SDC BASE PARTICIPANT requires of the SYSTEM OWNER to configure redundancy into the IT NETWORK.

— The ACCOMPANYING INFORMATION of the SDC BASE PARTICIPANT requires of the SYSTEM OWNER to provide an emergency power supply for IT NETWORK components.

5.3.5 Cybersecurity

RR1662: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL perform cybersecurity RISK MANAGEMENT.

NOTE—Fulfilling this requirement can be supported by applying standards such as IEC 81001-5-1 [B7] and specifications such as IEC TR 60601-4-5 [B8].

DR1579: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL declare the supported cryptographical protocols in the ACCOMPANYING INFORMATION.

NOTE 1—This supports the SYSTEM OWNER in verifying compatibility between SDC BASE PARTICIPANTs.

NOTE 2—Example: An SDC BASE PARTICIPANT only supports TLS 1.3 or higher.

The following requirements specify a set of universally applicable cybersecurity RISK MANAGEMENT tasks. They are necessary but not sufficient to satisfy RR1662 for a specific SDC BASE PARTICIPANT.

RR1133: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL consider the RISKs resulting from cybersecurity attacks from the IT NETWORK.

RR1135: The MANUFACTURER of an SDC BASE PROVIDER SHALL consider the cybersecurity RISKs resulting from access by BICEPS SERVICE CONSUMERs that are not authorized by the HEALTHCARE DELIVERY ORGANIZATION.

NOTE—Example of a RISK:

— A malicious attacker uses a BICEPS SERVICE CONSUMER not owned by the HEALTHCARE DELIVERY ORGANIZATION to attack an SDC BASE PROVIDER owned by the HEALTHCARE DELIVERY ORGANIZATION.

Example of a mitigation:

— The ACCOMPANYING INFORMATION of the SDC BASE PROVIDER requires of the HEALTHCARE DELIVERY ORGANIZATION to use allowlists to prevent access by unauthorized BICEPS SERVICE CONSUMERs.

The following example of a mitigation can reduce RESIDUAL RISKs but is not deemed appropriate to mitigate unacceptable RISKs:

— The ACCOMPANYING INFORMATION of the SDC BASE PROVIDER requires of the SYSTEM OWNER to connect the SDC BASE PROVIDER only to IT NETWORKs that are protected against unauthorized access.

RR1137: The MANUFACTURER of an SDC BASE CONSUMER SHALL consider the RISKs that result from unauthorized persons using the SDC BASE CONSUMER to get access to SDC BASE PROVIDERs.

RR1139: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL consider the RISKs resulting from the extraction and malicious use of the private key of the SDC BASE PARTICIPANT.

5.3.6 SDC PARTICIPANT ENSEMBLEs

The objective is for all SDC BASE PARTICIPANTs to allow for the CLINICAL USER to establish a single mental model of when and under which conditions SDC BASE PARTICIPANTs can or cannot execute SYSTEM FUNCTIONs together. This mental model amounts to:

— Devices are used for the care of specific patients at specific locations.

— Devices at the same location can be used together for the same patient.

DR1149: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL disclose in the ACCOMPANYING INFORMATION the means by which the SDC BASE PARTICIPANT can enter an SDC PARTICIPANT ENSEMBLE and any related limitations that impair execution of SYSTEM FUNCTIONs.

NOTE 1—Example: An SDC BASE PARTICIPANT can be limited to entering SDC PARTICIPANT ENSEMBLEs based on properties of the pm:LocationContextState such as pm:Category or pm:Identification/pm:Type.

NOTE 2—A SYSTEM OWNER can further restrict these means, e.g., according to hospital procedures.

RR1146: If an SDC BASE PARTICIPANT supports automatic inference of SDC PARTICIPANT ENSEMBLEs, the MANUFACTURER of the SDC BASE PARTICIPANT SHALL provide OBJECTIVE EVIDENCE that the CLINICAL USER understands that SDC BASE PARTICIPANTs assigned to the same location and/or the same patient can execute SYSTEM FUNCTIONs.

DR1152: If an SDC BASE PROVIDER supports location-inferred SDC PARTICIPANT ENSEMBLEs and the definition of location context information is in the responsibility of the SYSTEM OWNER, the MANUFACTURER of the SDC BASE PROVIDER SHALL provide instructions in the ACCOMPANYING INFORMATION to the effect that the location context information that is used for this purpose is unique to one patient at a time.

RR1154: For each SYSTEM FUNCTION an SDC BASE CONSUMER is intended to execute, the MANUFACTURER of the SDC BASE CONSUMER SHALL consider the RISKs resulting from unintended execution due to erroneously assuming that the SDC BASE CONSUMER is operating in the same SDC PARTICIPANT ENSEMBLE as the MDS of an SDC BASE PROVIDER.

NOTE 1—Examples of RISKs:

— After an SDC BASE PROVIDER's MDS has left an SDC PARTICIPANT ENSEMBLE, an SDC BASE CONSUMER continues to display physiological data from that MDS, which is collected from a different patient context than the SDC BASE CONSUMER is operated in.

— An SDC BASE CONSUMER continues to assume membership in a location-inferred SDC PARTICIPANT ENSEMBLE although the SDC BASE CONSUMER was moved to a different location.

NOTE 2—Examples of mitigations:

— An SDC BASE CONSUMER that initiates the execution of a SYSTEM FUNCTION together with an SDC BASE PROVIDER of the same SDC PARTICIPANT ENSEMBLE monitors the ensemble context of the SDC BASE PROVIDER's MDS for changes.

— An SDC BASE CONSUMER that initiates the execution of a SYSTEM FUNCTION together with an SDC BASE PROVIDER's MDS of the same SDC PARTICIPANT ENSEMBLE allows to display information indicating membership in the SDC PARTICIPANT ENSEMBLE, see TR1563 in 6.6.5.5.

RR1348: The MANUFACTURER of an SDC BASE PROVIDER SHALL consider the RISKs resulting from unintended execution of SYSTEM FUNCTIONs due to erroneous membership of an MDS in an SDC PARTICIPANT ENSEMBLE.

NOTE 1—The severity of the related RISKs depends on the SDC BASE PROVIDER's SYSTEM FUNCTION CONTRIBUTIONs.

NOTE 2—Besides technical causes, USE ERRORs leading to an erroneously associated pm:EnsembleContextState need to be considered.

NOTE 3—Examples of mitigations:

— When a mobile SDC BASE PROVIDER loses connection to mains supply or is turned on/off, it removes all instances of pm:Validator from its pm:LocationContextState and dissassociates its location-inferred pm:EnsembleContextState.

— When an SDC BASE PROVIDER is in standby or is turned on/off, it removes all instances of pm:Validator from its pm:PatientContextState and dissassociates its patient-inferred pm:EnsembleContextState.

— An SDC BASE PROVIDER allows for USERs to display the current location and patient context states.

RR1380: The MANUFACTURER of an SDC BASE PROVIDER SHALL consider the RISKs that result from precautionarily leaving an SDC PARTICIPANT ENSEMBLE.

NOTE—Leaving an SDC PARTICIPANT ENSEMBLE can lead to the loss of SYSTEM FUNCTIONs, e.g., alarm distribution. The resulting RISKs depend on the provided services and needs to be balanced against the RISKs resulting from erroneous membership in an SDC PARTICIPANT ENSEMBLE (cf. RR1348 in 5.3.6).

5.4 System use

RR1433: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL provide OBJECTIVE EVIDENCE that USERs understand that the SDC BASE PARTICIPANT is part of a networked system that could affect the CLINICAL FUNCTION of this and other BICEPS PARTICIPANTs.

RR1215: The MANUFACTURER of an SDC BASE CONSUMER SHALL prepare a SYSTEM FUNCTION USE SPECIFICATION for every SYSTEM FUNCTION the SDC BASE CONSUMER is intended to make available.

NOTE 1—The SYSTEM FUNCTION USE SPECIFICATION is stored in the usability engineering file.

NOTE 2—The SYSTEM FUNCTION USE SPECIFICATION of the SDC BASE CONSUMER can differ from the USE SPECIFICATION of SDC BASE PROVIDERs. Accordingly, every RISK that is related to the use as described in the SYSTEM FUNCTION USE SPECIFICATION of the SDC BASE CONSUMER is subject to USABILITY ENGINEERING.

NOTE 3—Different USER PROFILEs and USE ENVIRONMENTs need to be considered in the course of usability evaluation even if the INTENDED USE of a function remains the same between SDC BASE PROVIDER and SDC BASE CONSUMER.

NOTE 4—Example: A patient monitor that is used by many USER GROUPs with different skills and tasks can display data from MEDICAL DEVICEs with a more limited USER GROUP. The MANUFACTURER of the monitor would need to consider which use-related RISKs or usability issues can arise from making data available that was potentially unavailable to part of the USER GROUP before.

RR1030: The MANUFACTURER of an SDC BASE CONSUMER SHALL provide OBJECTIVE EVIDENCE for safe and effective use as described in the SYSTEM FUNCTION USE SPECIFICATION under NORMAL USE conditions.

NOTE 1—OBJECTIVE EVIDENCE is obtained by performing usability evaluation.

NOTE 2—NORMAL USE conditions include IT NETWORK failures that lead to loss of SYSTEM FUNCTIONs.

NOTE 3—This requirement can be fulfilled by applying recognized standards such as IEC 62366-1 [B4].

RR1025: If the MANUFACTURER of an SDC BASE CONSUMER demonstrates conformity to IEC 62366-1 [B4], the SYSTEM FUNCTION USE SPECIFICATION SHALL be part of the USE SPECIFICATION.

RR1430: If an SDC BASE CONSUMER is intended to display states of a BICEPS SERVICE PROVIDER or a patient condition according to its SYSTEM FUNCTION USE SPECIFICATION, the MANUFACTURER of the SDC BASE CONSUMER SHALL provide OBJECTIVE EVIDENCE that the USER is able to identify the displayed states of the BICEPS SERVICE PROVIDER or the patient condition.

NOTE 1—Whereas the BICEPS SERVICE PROVIDER is responsible for the validity of the provided data, it is not responsible for the usability as it does not necessarily display this data.

NOTE 2—Examples of SYSTEM FUNCTION USE SPECIFICATIONs:

- An SDC BASE PROVIDER shares ventilation settings and an SDC BASE CONSUMER declares in the SYSTEM FUNCTION USE SPECIFICATION that it displays ventilation settings. The MANUFACTURER of the SDC BASE CONSUMER needs to provide OBJECTIVE EVIDENCE that the USER is able to interpret the displayed ventilation settings correctly.
- An SDC BASE PROVIDER shares ventilation settings and an SDC BASE CONSUMER declares in the SYSTEM FUNCTION USE SPECIFICATION that it displays invasiveness of ventilation as a score that is calculated from ventilation settings. The MANUFACTURER of the SDC BASE CONSUMER has to provide OBJECTIVE EVIDENCE that the USER is able to interpret the score correctly.

RR1428: If an SDC BASE CONSUMER is intended to display the state of a BICEPS SERVICE PROVIDER or a patient condition, the MANUFACTURER of the SDC BASE CONSUMER SHALL consider the RISKs that result from USERs gaining a wrong understanding regarding the state of the BICEPS SERVICE PROVIDER or the patient condition.

NOTE—Examples of RISKs:

— The USER of an SDC BASE CONSUMER does not perceive that the state, e.g., a setting, of the BICEPS SERVICE PROVIDER was changed by another USER.
— The USER of an SDC BASE CONSUMER misinterprets displayed settings because there is no awareness of the state of a connected BICEPS SERVICE PROVIDER.
— The USER of an SDC BASE CONSUMER misinterprets displayed measurements because there is no awareness of settings affecting these measurements.
— The USER of an SDC BASE CONSUMER misinterprets the patient condition because relevant information is not being displayed.

Examples of mitigations:

— An SDC BASE CONSUMER notifies the USER when the state of a connected BICEPS SERVICE PROVIDER is changed from another location.
— An SDC BASE CONSUMER displays state information of a connected BICEPS SERVICE PROVIDER that is relevant for the interpretation of information on display.

RR1440: For each pm:ConceptDescription element provided by an SDC BASE PROVIDER, the MANUFACTURER of the SDC BASE PROVIDER SHALL provide OBJECTIVE EVIDENCE that the intended USERs of the SDC BASE PROVIDER understand the text that is referenced or provided therein.

NOTE 1—This applies regardless of whether an SDC BASE PROVIDER provides a LOCALIZATION SERVICE.

NOTE 2—The MANUFACTURER only verifies that the pm:ConceptDescription elements are understood in the SDC BASE PROVIDER's own context of use, e.g., they are displayed on a local/integrated graphical UI.

RR1442: If an SDC BASE CONSUMER is intended to display the state of a BICEPS SERVICE PROVIDER or a patient condition, the MANUFACTURER of the SDC BASE CONSUMER SHALL consider the RISKs that result from displaying the contents of pm:ConceptDescription provided by a BICEPS SERVICE PROVIDER.

NOTE—Examples of RISKs:

— Labels for settings or measurements derived from pm:ConceptDescription elements are misinterpreted when displayed in a different context.
— The SDC BASE CONSUMER displays illegible text because a pm:ConceptDescription contains characters that the SDC BASE CONSUMER cannot display on its UI.

RR1732: The MANUFACTURER of an SDC BASE PROVIDER SHALL provide OBJECTIVE EVIDENCE that for each provided pm:PhysicalConnectorInfo/pm:Label the intended USER of the SDC BASE PROVIDER is able to identify the corresponding physical connector.

NOTE—Physical connectors refer to, e.g., port, module, or sensor connectors; see 6.6.4.1.

RR1960: The MANUFACTURER of an SDC BASE CONSUMER SHALL consider the RISKs that result from using information received from device components while they do not have all of the following properties:

— **@SafetyClassification ∈ { MedA, MedB, MedC },**
— **@ActivationState ∈ { On, StndBy }.**

6. Technical design

6.1 SDC PARTICIPANT KEY PURPOSE conformity assurance

TR1633: An SDC BASE PROVIDER SHALL only perform TLS handshakes if its own CERTIFICATE includes the SDC BASE PROVIDER PKP OID in its EKU extension.

TR1634: An SDC BASE CONSUMER SHALL only perform TLS handshakes if its own CERTIFICATE includes the SDC BASE CONSUMER PKP OID in its EKU extension.

TR1459: An SDC BASE PARTICIPANT SHALL only perform TLS handshakes if the EKU extension of its own CERTIFICATE includes the OIDs of all SDC PARTICIPANT KEY PURPOSEs from any additional SDC PKP STANDARDs that the SDC BASE PARTICIPANT demonstrates conformity to.

TR1582: An SDC BASE PARTICIPANT SHOULD only perform TLS handshakes if the EKU extension of its own CERTIFICATE includes the OIDs of all additional SDC PARTICIPANT KEY PURPOSEs that the SDC BASE PARTICIPANT demonstrates conformity to.

6.2 Standards conformity indication in the CONTAINMENT TREE

This subclause supplements 5.1.2.3. It specifies how an SDC BASE PROVIDER leverages the pm:ProductionSpecification element to indicate conformity to sets of requirements.

The mechanism described in this subclause can be used for all sets of requirements that are identifiable by means of an Object Identifier (OID) including, but not limited to, SDC PARTICIPANT KEY PURPOSEs and particular standards of the IEC 60601-2 series.

TR0108: If the MANUFACTURER of an SDC BASE PROVIDER determines a set of requirements that the SDC BASE PROVIDER or a part of it conforms to, the SDC BASE PROVIDER SHOULD attach a pm:ProductionSpecification element with pm:SpecType = MDC_ATTR_SYS_TYPE_SPEC_LIST and pm:ProductionSpec being an OID identifying the set of requirements to each BICEPS CONTAINMENT TREE ENTRY that is the root of a BICEPS CONTAINMENT SUBTREE which contains only nodes representing parts that conform to this set of requirements and which is not part of larger BICEPS CONTAINMENT SUBTREE that also fulfills this condition.

NOTE 1—An OID assignment that represents a set of requirements can be either proprietary or standardized.

NOTE 2—Standardized OIDs can be provided by other SDC PKP STANDARDs, IEEE 11073 Device Specializations, or applicable particular standards.

NOTE 3—Conformity to a particular standard is typically attributed to the entire product. Some requirements can, however, not be applicable to the SDC BASE PROVIDER, e.g., display requirements if the provider only determines and provides values but does not have a display of its own.

NOTE 4—Example: A multifunction patient monitor has multiple VMDs, each of which conforms to a particular standard, e.g., for pulse oximetry or electrocardiography. This conformity is indicated by pm:ProductionSpecification elements at the VMD level.

6.3 Cybersecurity

TR1164: An SDC BASE PROVIDER SHALL use secured channels to protect all of its BICEPS SERVICEs against unauthenticated access.

NOTE 1—Depending on the actual transport technology binding, a secure channel is implemented, e.g., by using a TLS-over-TCP connection.

NOTE 2—This further restricts IEEE Std 11073-20701-2018, R0043 in 10.1 [B11], by requiring consistent protection of all BICEPS SERVICEs.

TR1134: CLINICAL FUNCTIONs of an SDC BASE PARTICIPANT except for network-related functionality SHALL be designed in a way that they are not impaired by the IT NETWORK communication, including but not limited to:

- **ARP floods,**
- **ICMP floods,**
- **TCP SYN floods,**
- **UDP floods,**
- **Floods of TLS connection requests,**
- **Frequent corruption (such that it is detected by TLS) of SDC messages.**

NOTE 1—Network-related functionality includes the provision and consumption of SYSTEM FUNCTION CONTRIBUTIONs.

NOTE 2—The design of other network-related clinical functionality, e.g., DICOM image exchange, is not within the scope of this standard.

6.4 Logging

Logging is the automatic creation of stored data records with the purpose of tracing software process states, especially in case of errors. This subclause defines a foundational set of logging requirements for SDC BASE PARTICIPANTs in order to facilitate forensic analysis of communication failures.

The requirements in this subclause pertain to logs of individual SDC BASE PARTICIPANTs. Requirements that address components dedicated to forensic data logging of an entire HEALTH IT SYSTEM are out of scope of this standard, but can be found, e.g., in ANSI/AAMI 2700-2-1 [B1].

TR0216: For every TLS-based sequence of SDC message exchanges, an SDC BASE PARTICIPANT SHALL log:

- **Date and time of the handshake,**
- **Date and time when the last message of the sequence has been exchanged,**
- **As to whether the end of the sequence of SDC messages was mutually acknowledged,**
- **Addressing information of the other BICEPS PARTICIPANT,**
- **DISTINGUISHED NAME and EXTENDED KEY USAGE of the other BICEPS PARTICIPANT, and**
- **TLS version and cypher suite negotiated during the handshake.**

NOTE 1—This requires logging the beginning and the end of every sequence of SDC messages.

NOTE 2—For a TCP connection, the end of a sequence of SDC messages is specified as the closing of the socket.

NOTE 3—For a TCP connection, addressing information is the destination IP address and port.

TR0217: For each attempt of an authenticated BICEPS SERVICE CONSUMER to use a BICEPS SERVICE that it is not authorized to use, the SDC BASE PROVIDER SHALL log:

- **Date and time of the attempt,**
- **Addressing information of the BICEPS SERVICE CONSUMER,**
- **DISTINGUISHED NAME and EXTENDED KEY USAGE of the BICEPS SERVICE CONSUMER, and**
- **Rationale for the denial of access.**

NOTE—For a TCP connection, addressing information is the destination IP address and port.

TR0223: An SDC BASE PARTICIPANT SHALL provide means for the ADMINISTRATOR to retrieve log records required by applicable SDC PKP STANDARDs for analysis.

DR1601: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL declare in the ACCOMPANYING INFORMATION the means for the ADMINISTRATOR to retrieve log records required by applicable SDC PKP STANDARDs.

TR0225: An SDC BASE PARTICIPANT SHOULD provide logs in RFC 5424 [B22] conforming Syslog format.

NOTE—To fulfil this requirement, the MANUFACTURER can also provide tools including documentation to convert log records into RFC 5424 [B22] conforming Syslog format.

TR0229: An SDC BASE PARTICIPANT SHALL protect the log records required by applicable SDC PKP STANDARDs against tampering.

TR0916: An SDC BASE PARTICIPANT SHALL log the identifying information of its configured time source at the time of initial synchronization and upon subsequent time source changes.

NOTE—The identifying information of an NTP server is its network address.

TR1340: An SDC BASE PARTICIPANT SHOULD log each non-slewing adjustment of the local clock.

NOTE—The need for a non-slewing time adjustment is typically the result of a hardware failure or operator error.

TR0917: An SDC BASE PARTICIPANT SHALL attach UTC timestamps at least in millisecond resolution to all log entries.

NOTE 1—See, for example, RFC 3339 [B20].

NOTE 2—UTC has to be determinable from the log message, i.e., it is permitted to attach the local time with the local offset to that end.

6.5 Maximum load conditions

This subclause defines requirements for the operational status of an SDC BASE PARTICIPANT under IT NETWORK MAXIMUM LOAD CONDITIONs.

TR0054: An SDC BASE PARTICIPANT SHALL provide its INTENDED SYSTEM FUNCTION CONTRIBUTIONs under MAXIMUM LOAD CONDITIONs.

6.6 Participant model

TR1949: When an SDC BASE PROVIDER inserts, changes, or removes a pm:ProductionSpecification element, the SDC BASE PROVIDER SHALL set pm:Mdib/pm:MdibVersionGroup/@SequenceId to a new value.

TR1590: For each MDS, an SDC BASE PROVIDER SHOULD set pm:ClockDescriptor/@SafetyClassification to the same value as that of the most critical BICEPS CONTAINMENT TREE ENTRY of the MDS.

NOTE—BICEPS SERVICE CONSUMERs compare clock information of an MDS with their own clock.

6.6.1 Instance identifiers

Instance identifiers as defined in IEEE Std 11073-10207 are used to uniquely identify instances of physical or virtual entities. They comprise several elements: the root uniquely specifies a system of reference (e.g., a hospital) whereas the extension specifies the entity within that system (e.g., an actual patient or an order for a procedure). In contrast, the type specifies the kind of the identifier.

TR0886: An SDC BASE PARTICIPANT SHALL limit values of pm:InstanceIdentifier/@Root to those matching the form scheme ":" hier-part as defined in RFC 3986 Clause 3 [B21] and scheme ":" hier_part as defined in RFC 2396 Clause 3 [B19] except for "biceps.uri.unk" and "sdc.ctxt.loc.detail".

NOTE 1—Query and fragment are not part of the root. They can, however, be part of the @Extension.

NOTE 2—There are cases in which the @Extension continues the URI path component.

NOTE 3—This further restricts IEEE Std 11073-10207-2017, B.227 [B10].

TR1517: If two instances of pm:InstanceIdentifier have identical values of @Extension and at least one of them has @Root = biceps.uri.unk or no @Root, an SDC BASE PARTICIPANT SHALL NOT assume that they refer to the same entity.

6.6.2 Coded values

TR1814: For each pm:CodedValue and pm:Translation, if there are one or more standardized URIs that identify the coding system including the coding system version of the code, an SDC BASE PARTICIPANT SHALL set @CodingSystem to one such URI and provide no @CodingSystemVersion.

NOTE 1—Example: urn:oid:1.3.111.2.11073.10101.3 identifies version 3 of the IEEE Std 11073-10101 Nomenclature.

NOTE 2—@CodingSystemVersion has no uniform syntax whereas the @CodingSystem is commonly referred to by means of an OID.

TR1840: For each pm:CodedValue and pm:Translation, an SDC BASE PARTICIPANT SHALL NOT set @CodingSystem to a URI that identifies IEEE 11073-10101-2004 or IEEE 11073-10101a-2015.

NOTE 1—SDC BASE PARTICIPANTs can use IEEE Std 11073-10101-2019 [B9] or subsequent versions.

NOTE 2—TR1840 obsoletes IEEE Std 11073-10207-2017, R0128 in 5.2.3 [B10].

TR1842: For each pm:CodedValue where @Code is defined in IEEE Std 11073-10101, an SDC BASE PARTICIPANT SHALL set @CodingSystem = urn:oid:1.3.111.2.11073.10101.n with n ≥ 3.

NOTE—To increase interoperability, this OID arc is mandatory for identifying IEEE Std 11073-10101. If an SDC BASE PARTICIPANT needs to identify IEEE Std 11073-10101 by an OID from any other arc, e.g., for compatibility with legacy equipment or with an HL7 gateway, it can add a pm:Translation to the pm:CodedValue.

6.6.3 Private code semantics

IEEE Std 11073-10207-2017, R0008 in 5.2.3 [B10] recommends that a BICEPS PARTICIPANT populates pm:CodedValue with a code from a standardized coding system.

TR1357: If there is no standardized code to convey semantics, an SDC BASE PARTICIPANT SHOULD populate pm:CodedValue with a private code as detailed in IEEE Std 11073-10101.

TR1358: If an SDC BASE PARTICIPANT uses a private code as detailed in IEEE Std 11073-10101, the SDC BASE PARTICIPANT SHALL refer to its definition by providing a pm:Translation with a @CodingSystem that uniquely identifies the private coding system that contains the code.

NOTE—This implies that a MANUFACTURER that needs to use private codes has to keep a private coding system for these codes. Following the concept of private codes that is defined in IEEE Std 11073-10101, a MANUFACTURER introduces and maintains a set of codes that adhere to the principles of the IEEE 11073 Nomenclature standards.

6.6.4 Device components

TR0912: On each intended shutdown of an SDC BASE PROVIDER, for each pm:MdsState element, the SDC BASE PROVIDER SHALL set @ActivationState = Shtdn.

TR1279: Before each intended shutdown of an SDC BASE PROVIDER, for each pm:MdsState of the SDC BASE PROVIDER, the SDC BASE PROVIDER SHALL send the pm:MdsState element with the latest @StateVersion to each BICEPS SERVICE CONSUMER subscribed to msg:AbstractComponentReport messages.

NOTE—This includes the information about the state change required by TR0912 in 6.6.4.

TR0251: If any of the following information items are available, an SDC BASE PROVIDER SHALL provide them using pm:MetaData:

- **pm:Manufacturer**
- **pm:ModelName**
- **pm:ModelNumber**
- **pm:SerialNumber**

TR1373: For each pm:AbstractDeviceComponentDescriptor that is the root node of a BICEPS CONTAINMENT SUBTREE representing a component with a software version, an SDC BASE PROVIDER SHALL provide the software version in pm:AbstractDeviceComponentDescriptor/pm:ProductionSpecification with @SpecType = MDC_ID_PROD_SPEC_SW.

TR1374: For each pm:AbstractDeviceComponentDescriptor that is the root node of a BICEPS CONTAINMENT SUBTREE representing a component with a known hardware version, an SDC BASE PROVIDER SHALL provide the hardware version in pm:AbstractDeviceComponentDescriptor/pm:ProductionSpecification with @SpecType = MDC_ID_PROD_SPEC_HW.

TR0252: For each of its UDIs, an SDC BASE PROVIDER SHOULD provide it using pm:MetaData/pm:Udi.

6.6.4.1 Physical connectors

The pm:PhysicalConnectorInfo element represents a connector or port, to which a module, e.g., a sensor or actuator, can be connected. The pm:PhysicalConnectorInfo is part of the pm:AbstractComponentState or pm:AbstractMetricState element.

TR1436: If a pm:MdsDescriptor contains multiple pm:VmdDescriptor elements that are of semantically equivalent pm:Type and while the corresponding pm:VmdState/@ActivationState ∈ { On, StndBy, Shtdn, Fail }, an SDC BASE PROVIDER SHALL provide for each of these pm:VmdState elements a pm:PhysicalConnectorInfo/@Number that is unique to these elements.

TR1437: If a pm:VmdDescriptor contains multiple pm:ChannelDescriptor elements that are of semantically equivalent pm:Type and while the corresponding pm:ChannelState/@ActivationState ∈ { On, StndBy, Shtdn, Fail }, an SDC BASE PROVIDER SHALL provide for each of these pm:ChannelState elements a pm:PhysicalConnectorInfo/@Number that is unique to these elements.

TR1438: If a pm:ChannelDescriptor contains multiple pm:AbstractMetricDescriptor elements that are of the same @MetricCategory and of semantically equivalent pm:Type and pm:Unit and while the corresponding pm:AbstractMetricState/@ActivationState ∈ { On, StndBy, Shtdn, Fail }, an SDC BASE PROVIDER SHALL provide for each of these pm:AbstractMetricState elements a pm:PhysicalConnectorInfo/@Number that is unique to these elements.

TR1733: The MANUFACTURER of an SDC BASE PROVIDER SHOULD verify that every pm:PhysicalConnectorInfo/pm:Label matches the label on the corresponding hardware unit.

6.6.4.2 Removable subsystems

When a REMOVABLE SUBSYSTEM is physically connected, it is represented in the MDIB of the BICEPS SERVICE PROVIDER. In some cases, there is a need for representation of a REMOVABLE SUBSYSTEM even when it is not connected, e.g., for pre-configuring settings that are automatically applied when the REMOVABLE SUBSYSTEM is connected.

TR1594: For each pm:AbstractDeviceComponentDescriptor that represents a REMOVABLE SUBSYSTEM and while the REMOVABLE SUBSYSTEM is not physically connected to the SDC BASE PROVIDER, the SDC BASE PROVIDER SHALL set the pm:AbstractDeviceComponentState/@ActivationState ∈ { NotRdy, Off }.

NOTE—Other reasons for being unavailable than the removal of the REMOVABLE SUBSYSTEM can also be expressed by pm:AbstractDeviceComponentState/@ActivationState ∈ { NotRdy, Off }.

TR1593: For each pm:AbstractDeviceComponentDescriptor that represents a REMOVABLE SUBSYSTEM and while the REMOVABLE SUBSYSTEM is not physically connected to the SDC BASE PROVIDER, the SDC BASE PROVIDER SHALL NOT provide the pm:AbstractDeviceComponentState/pm:PhysicalConnector element.

6.6.5 Context

TR1959: While pm:SystemContextState/@ActivationState of an MDS is set to Off, for each pm:AbstractContextState of that MDS, an SDC BASE PROVIDER SHALL set @ContextAssociation = No.

TR1304: For each pm:AbstractContextState, while @ContextAssociation = Assoc, an SDC BASE PROVIDER SHALL provide a non-empty instance of pm:AbstractContextState/pm:Identification.

TR1636: For each pm:AbstractContextState, while @ContextAssociation = Assoc, an SDC BASE PROVIDER SHALL provide @BindingMdibVersion and @BindingStartTime.

TR1637: For each pm:AbstractContextState, while @ContextAssociation = Assoc, an SDC BASE PROVIDER SHALL NOT provide @UnbindingMdibVersion and @BindingEndTime.

TR1638: For each pm:AbstractContextState, while @ContextAssociation = Dis, an SDC BASE PROVIDER SHALL provide @BindingMdibVersion, @BindingStartTime, @UnbindingMdibVersion, and @BindingEndTime.

TR1639: For each pm:AbstractContextState, while @ContextAssociation = Pre, an SDC BASE PROVIDER SHALL NOT provide @BindingMdibVersion, @BindingStartTime, @UnbindingMdibVersion, and @BindingEndTime.

TR1470: An SDC BASE PROVIDER SHALL change @ContextAssociation according to the transitions in Figure 1.

NOTE—This further restricts IEEE Std 11073-10207-2017, B.10 [B10].

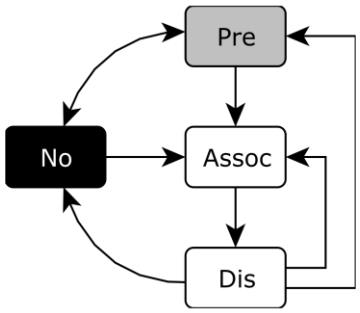

Figure 1—Acceptable context association state transitions

TR1461: While pm:AbstractContextState/@ContextAssociation = Assoc, an SDC BASE PROVIDER SHALL NOT remove or change any instance of pm:Identification within this pm:AbstractContextState.

NOTE 1—The SDC BASE PROVIDER has to set pm:AbstractContextState/@ContextAssociation = Dis in advance.

NOTE 2—Adding an additional instance that identifies the same entity does not require prior disassociation.

6.6.5.1 Context validation

The presence of an instance of pm:Validator expresses that an identifiable actor (e.g., a USER or a BICEPS PARTICIPANT) has confirmed the correctness of its context association state.

The pm:Validator/@Root and pm:Validator/@Extension attributes are used to identify a specific validator entity, e.g., the person John Doe, whereas pm:Validator/pm:Type is used to describe the kind of validator, e.g., a nurse, biomed, etc.

TR1544: If the identity of a validator is known, an SDC BASE PARTICIPANT SHALL provide the validator's complete unique identifier using pm:Validator.

TR1499: If the identity of a validator is unknown, an SDC BASE PARTICIPANT SHALL set pm:Validator/@Root = urn:oid:2.16.840.1.113883.5.1008 and pm:Validator/@Extension = UNK.

NOTE—It cannot reasonably be expected of every SDC BASE PARTICIPANT to be able to identify the actor, e.g., the USER, that confirmed correctness of its context association state.

TR0855: For each pm:AbstractContextState/pm:Validator, an SDC BASE PARTICIPANT SHALL provide pm:Validator/pm:Type to describe the kind of actor that validated the context association state.

NOTE—An extensible value set for validator types is given in Table B.1.

TR1500: While a pm:AbstractContextState contains at least one pm:Validator, an SDC BASE PARTICIPANT SHALL provide one or more pm:Identification elements for this pm:AbstractContextState where @Root defines the system of reference, @Extension contains the identifier, and @Extension is not set to a null value.

NOTE 1—The @Root can contain, for example, the unique identification of an HDO.

NOTE 2—The @Extension can contain, for example, the patient identifier assigned by the HDO.

NOTE 3—A null value indicates that a value is missing, omitted, incomplete, or improper. It is not to be confused with a value of 0 (zero). The encoding of a null value depends on the system of reference.

TR1467: When a pm:AbstractContextState ceases to appropriately represent context information of the physical or logical component represented by an MDS, the SDC BASE PROVIDER SHALL change every corresponding @ContextAssociation to Dis and identify a validator for this new association state.

NOTE—The validator is the identifiable actor, e.g., the SDC BASE PROVIDER itself or its USER, that validates the context disassociation.

TR1465: If correctness of an MDS's context association state can no longer be verified, the SDC BASE PROVIDER SHALL remove all instances of pm:Validator from this context state.

NOTE 1—The removal of the pm:Validator elements expresses uncertainty about the association state in contrast to the deliberate disassociation that is the subject of TR1467.

NOTE 2—Examples include RISK mitigations such as invalidating the association of a pm:LocationContextState for reasons of precaution when the component loses connection to its mains power supply.

6.6.5.2 Patient context

For many use cases, it is beneficial to have validated patient information. In addition to the inference of SDC PARTICIPANT ENSEMBLEs, patient identifiers can be used to combine data from previous visits of the same patient, to maintain an alarm history for a patient visit, or to visualize trend data from an episode of care. Patient identifiers are often machine-readable as well as suitable for being displayed to USERs. Examples of identifiers that can be used for these purposes include

— Medical record number and social security number that identify the patient,
— Visit identifier and case identifier that identify a patient visit, and
— Episode identfier that identifies an episode of care of a patient.

TR0997: If an SDC BASE PARTICIPANT is able to determine the type of a pm:PatientContextState/pm:Identification element, the SDC BASE PARTICIPANT SHALL set pm:Identification/pm:Type.

NOTE—Example: For a patient identifier, pm:Type/@Code = MDC_ATTR_PT_ID is appropriate.

TR0999: If an SDC BASE PARTICIPANT is intended to transmit the patient identification of a neonate's mother, the SDC BASE PARTICIPANT SHALL use pm:NeonatalPatientDemographicsCoreData/pm:Mother/pm:Identification with pm:Type/@Code = MDC_ATTR_ID_PT_MOTHER.

6.6.5.3 Workflow context

IEEE Std 11073-10207 defines the pm:WorkflowDetail element that can be used to convey information about a workflow step, e.g., an order for a diagnostic procedure from a health IT element outside of the SDC SYSTEM. Its child elements are mostly optional and no conclusion can be drawn from their absence.

This section introduces requirements to share information that is available, but it does not require SDC BASE PARTICIPANTs to act on this information. The need for consideration is highly dependent on the individual INTENDED USE and CLINICAL FUNCTION. Therefore, no general statement can be made.

TR1912: When an SDC BASE PARTICIPANT sets pm:WorkflowContextState/pm:WorkflowDetail, if the SDC BASE PARTICIPANT has information about known or suspected hazards originating from the patient that is represented by pm:WorkflowDetail/pm:Patient, the SDC BASE PARTICIPANT SHALL set pm:WorkflowDetail/pm:DangerCode to represent this information.

NOTE—Example of a hazard: The patient has an infectious disease.

TR1914: When an SDC BASE PARTICIPANT sets pm:WorkflowContextState/pm:WorkflowDetail, if the SDC BASE PARTICIPANT has additional clinical information that is relevant to the workflow step represented by the pm:WorkflowContextState, the SDC BASE PARTICIPANT SHALL set pm:WorkflowDetail/pm:RelevantClinicalInfo to represent this information.

NOTE—Clinical information is considered additional for the purpose of this requirement when it is not conveyed by other means such as a metric state.

6.6.5.4 SDC PARTICIPANT ENSEMBLEs

The pm:EnsembleContextState elements of a BICEPS SERVICE PROVIDER express logical groups in which the BICEPS SERVICE PROVIDER is being operated.

Annex C provides examples of SDC PARTICIPANT ENSEMBLEs and interaction therein.

6.6.5.5 Ensemble membership and indication

TR0863: To indicate membership of an MDS in an SDC PARTICIPANT ENSEMBLE, an SDC BASE PROVIDER SHALL use pm:EnsembleContextState/pm:Identification with pm:EnsembleContextState/@ContextAssociation = Assoc.

NOTE—An MDS can be a member of more than one SDC PARTICIPANT ENSEMBLEs at the same time.

TR1563: An SDC BASE PARTICIPANT SHOULD allow for USERs to display its current SDC PARTICIPANT ENSEMBLE membership states.

There are multiple ways for SDC BASE PARTICIPANTs to join SDC PARTICIPANT ENSEMBLEs actively or passively.

TR0871: For each SDC PARTICIPANT ENSEMBLE of its MDSs, an SDC BASE PROVIDER SHALL provide information about the kind of the SDC PARTICIPANT ENSEMBLE through pm:EnsembleContextDescriptor/pm:Type.

NOTE 1—This can include information about the means by which an MDS enters the SDC PARTICIPANT ENSEMBLE.

NOTE 2—SDC BASE PARTICIPANTs can be added to ensembles for example by automatic inference, USER interaction, external control, or derivation by technical means.

NOTE 3—Additional information about the state, e.g., the type of location from which the ensemble is inferred, can be conveyed using pm:EnsembleContextState/pm:Category.

TR0874: For each of its pm:EnsembleContextState elements that indicates membership in an SDC PARTICIPANT ENSEMBLE with @ContextAssociation = Assoc, an SDC BASE PROVIDER SHALL provide one or more pm:EnsembleContextState/pm:Validator elements identifying the actors that confirmed the correctness of membership in the SDC PARTICIPANT ENSEMBLE.

NOTE—In case of automatically inferred ensembles, the SDC BASE PROVIDER can identify itself as the actor that validated the pm:EnsembleContextState as described in TR0855 in 6.6.5.1.

TR0973: When the membership in an SDC PARTICIPANT ENSEMBLE ends, the SDC BASE PROVIDER SHALL change the pm:EnsembleContextState/@ContextAssociation from Assoc to Dis immediately.

NOTE—Membership can end, for example, when the pm:Validator is removed from a pm:AbstractContextState from which an SDC PARTICIPANT ENSEMBLE is inferred.

6.6.5.6 Ensemble membership interpretation

SDC PARTICIPANT ENSEMBLEs are used by SDC BASE PARTICIPANTs to determine as to whether they are safe to exchange specific information with other SDC BASE PARTICIPANTs.

TR0879: An SDC BASE CONSUMER SHALL only initiate the execution of a SYSTEM FUNCTION with an SDC BASE PROVIDER if the SDC BASE CONSUMER is able to interpret one or more validated pm:EnsembleContextState/pm:Identification elements with @ContextAssociation = Assoc and the corresponding pm:EnsembleContextDescriptor/pm:Type of the MDS that provides the SDC BASE PROVIDER's SYSTEM FUNCTION CONTRIBUTION.

NOTE—"Interpret" in this case means that the SDC BASE CONSUMER has to understand that it is operating in the same SDC PARTICIPANT ENSEMBLE as the MDS of an SDC BASE PROVIDER when executing a SYSTEM FUNCTION.

TR0990: An SDC BASE CONSUMER SHOULD only initiate the execution of a SYSTEM FUNCTION with an SDC BASE PROVIDER if the SDC BASE CONSUMER is able to interpret one or more validated pm:EnsembleContextState/pm:Identification elements with @ContextAssociation = Assoc and the corresponding pm:EnsembleContextDescriptor/pm:Type/@Code ∈ { MDC_IDT_ENSEMBLE_LOCATION_INFERRED, MDC_IDT_ENSEMBLE_PATIENT_INFERRED } of the MDS that provides the SDC BASE PROVIDER's SYSTEM FUNCTION CONTRIBUTION.

NOTE 1—"Interpret" in this case means that the SDC BASE CONSUMER has to understand that it is operating in the same SDC PARTICIPANT ENSEMBLE as the MDS of an SDC BASE PROVIDER when executing a SYSTEM FUNCTION.

NOTE 2—SDC BASE PROVIDERs that are unable to handle patient and location information, e.g., headless mobile providers, can provide SYSTEM FUNCTION CONTRIBUTIONs if an SDC BASE CONSUMER is able to interpret another type of pm:EnsembleContextState/pm:Identification, e.g., an invariable SDC PARTICIPANT ENSEMBLE.

NOTE 3—TR0990 only affects CLINICAL FUNCTIONs. Other types of SDC PARTICIPANT ENSEMBLEs can be used for non-clinical purposes.

6.6.5.7 Ensemble membership inference

The use of automatically inferred SDC PARTICIPANT ENSEMBLEs makes it possible to merge and separate bigger ensembles. For example, all participants that are members of a location-inferred ensemble could temporarily join a patient-inferred ensemble for as long as the patient is at the specified location.

In practice, this can be implemented as a single USER interaction that confirms the binding between patient and location, followed by automatic distribution of patient information to every member of the location-inferred ensemble. In the same way, the members can be released from the patient when the binding ends.

TR0866: If an SDC BASE PROVIDER is intended to execute one or more SYSTEM FUNCTIONs with other SDC BASE PARTICIPANTs that operate in the same location, the SDC BASE PROVIDER SHOULD infer membership of the MDS that provides the SDC BASE PROVIDER's INTENDED SYSTEM FUNCTION CONTRIBUTION in an SDC PARTICIPANT ENSEMBLE by duplicating its pm:LocationContextState/pm:Identification to a pm:EnsembleContextState/pm:Identification with pm:EnsembleContextDescriptor/pm:Type/@Code = MDC_IDT_ENSEMBLE_LOCATION_INFERRED.

TR1151: If the physical location represented by the pm:LocationContextState of an MDS of an SDC BASE PROVIDER allows for more than one associated patient at the same time, the SDC BASE PROVIDER SHALL NOT infer membership of this MDS in an SDC PARTICIPANT ENSEMBLE from this pm:LocationContextState.

NOTE—If an SDC BASE CONSUMER and an MDS of an SDC BASE PROVIDER are members of the same location-inferred SDC PARTICIPANT ENSEMBLE, the SDC BASE CONSUMER can therefore infer that they are associated to the same patient.

TR0867: If an SDC BASE PROVIDER is intended to execute one or more SYSTEM FUNCTIONs with other SDC BASE PARTICIPANTs that operate on the same patient, the SDC BASE PROVIDER SHOULD infer membership of the MDS that provides the SDC BASE PROVIDER's INTENDED SYSTEM FUNCTION CONTRIBUTION in an SDC PARTICIPANT ENSEMBLE by duplicating its pm:PatientContextState/pm:Identification to a pm:EnsembleContextState/pm:Identification with pm:EnsembleContextDescriptor/pm:Type/@Code = MDC_IDT_ENSEMBLE_PATIENT_INFERRED.

TR0877: If a pm:AbstractContextState is not validated, an SDC BASE PROVIDER SHALL NOT infer membership by duplicating this pm:AbstractContextState/pm:Identification to a pm:EnsembleContextState/pm:Identification.

TR0873: If an SDC BASE PROVIDER infers membership of an MDS in an SDC PARTICIPANT ENSEMBLE, the SDC BASE PROVIDER SHALL set the inferred pm:EnsembleContextState/@ContextAssociation = Assoc only for as long as the pm:AbstractContextState from which it is inferred is also associated and validated.

NOTE—This implies that the @BindingMdibVersion of the inferred pm:EnsembleContextState is always greater than or equal to the @BindingMdibVersion of the pm:AbstractContextState from which it is inferred.

TR0974: An SDC BASE PROVIDER SHALL NOT allow for a USER to create or modify a pm:EnsembleContextState that belongs to a pm:EnsembleContextDescriptor with pm:Type/@Code of MDC_IDT_ENSEMBLE_LOCATION_INFERRED or MDC_IDT_ENSEMBLE_PATIENT_INFERRED with the exception of disassociating it.

NOTE—Automatically inferred ensembles are thereby kept separate from those created by USERs. USERs can instead set a patient context or location context to allow for automatic inference or they can create an ensemble context of a different type.

TR1303: An SDC BASE PROVIDER SHALL NOT allow for a BICEPS SERVICE CONSUMER to create or modify a pm:EnsembleContextState that belongs to a pm:EnsembleContextDescriptor with pm:Type/@Code of

MDC_IDT_ENSEMBLE_LOCATION_INFERRED or MDC_IDT_ENSEMBLE_PATIENT_INFERRED with the exception of disassociating it.

NOTE—Automatically inferred ensembles are thereby kept separate from those created through external control. External control consumers can instead set a patient context or location context to allow for automatic inference or they can create an ensemble context of a different type.

TR0993: If an SDC BASE PARTICIPANT is intended to allow for a USER to manage SDC PARTICIPANT ENSEMBLE membership of its own or any other MDS, the SDC BASE PARTICIPANT SHOULD allow for the display, modification, and validation of pm:LocationContextState, pm:PatientContextState, or both in order to facilitate SDC PARTICIPANT ENSEMBLE membership inference.

NOTE 1—Rather than to set or change ensemble membership directly, the SDC BASE PARTICIPANT enables a USER to set or change a patient and location context from which ensemble membership can be inferred.

NOTE 2—Automatic membership inference, association, and disassociation is preferred over manually orchestrating SDC PARTICIPANT ENSEMBLEs for the use of CLINICAL FUNCTIONs.

NOTE 3—For display purposes, the pm:LocationContextState/pm:LocationDetail and pm:PatientContextState/pm:CoreData are preferred as they contain human-readable information for identifying the context state. If these are ambiguous or not provided, the SDC BASE PARTICIPANT can display pm:AbstractContextState/pm:Identification instead.

6.7 Extension model

TR1490: If an EXTENSION modifies the meaning specified by pm:Type of the parent element that contains the EXTENSION or of any other element of the BICEPS CONTAINMENT SUBTREE that has this parent element as its root, an SDC BASE PARTICIPANT SHALL mark the EXTENSION with @ext:MustUnderstand = true.

NOTE 1—@ext:MustUnderstand = false means that the parent element that contains the EXTENSION can safely be processed without evaluating the EXTENSION.

NOTE 2—Example of an EXTENSION with @ext:MustUnderstand = false: Information about whether or how an SDC BASE PROVIDER displays a parameter to a USER.

TR1922: An SDC BASE PARTICIPANT SHALL NOT include an EXTENSION with @ext:MustUnderstand = true in an element that is derived from pm:AbstractState.

NOTE—Therefore a descriptor update is required if the need for such an EXTENSION is determined at runtime.

TR0765: An SDC BASE PROVIDER SHALL NOT use an EXTENSION with @ext:MustUnderstand = true to modify the meaning specified by pm:Type of any BICEPS CONTAINMENT TREE ENTRY outside the BICEPS CONTAINMENT SUBTREE that has as its root the BICEPS CONTAINMENT TREE ENTRY in which the EXTENSION is included.

NOTE 1—From this it follows that a BICEPS SERVICE CONSUMER can still interpret parts of the MDIB even if there are EXTENSIONs marked with @ext:MustUnderstand = true.

NOTE 2—An occurrence of pm:Relation does not change this rule, i.e., EXTENSIONs with @ext:MustUnderstand = true do not affect BICEPS CONTAINMENT TREE ENTRIEs in other subtrees that are connected by means of a pm:Relation.

NOTE 3—If a pm:Relation contains an EXTENSION with @ext:MustUnderstand = true, this EXTENSION can only modify the meaning specified by @Kind or pm:Code of the pm:Relation but neither of its parent metric nor of its @Entries.

TR1342: If an SDC BASE CONSUMER is unable to interpret an EXTENSION of a BICEPS SERVICE PROVIDER with @ext:MustUnderstand = true, the SDC BASE CONSUMER SHALL NOT use the BICEPS CONTAINMENT SUBTREE that has as its root the BICEPS CONTAINMENT TREE ENTRY in which the EXTENSION is included for the execution of any SYSTEM FUNCTION.

6.8 Localization

TR1480: An SDC BASE CONSUMER MAY translate concepts/types by itself and provide texts/labels based on internal text resources.

NOTE—This allows SDC BASE CONSUMERs to rely on their own translations opposed to translations that are provided by BICEPS SERVICE PROVIDERs. By providing translations of concepts/types itself, SDC BASE CONSUMERs can create a consistent view of data from different BICEPS SERVICE PROVIDERs of different MANUFACTURERs.

TR0280: If an SDC BASE PROVIDER's MDS represents a component with a UI, pm:MdsState/@Lang SHALL correspond to the UI language.

NOTE—If the SDC BASE PROVIDER cannot determine the UI language, it can set pm:MdsState/@Lang = und as defined in ISO 639 [B15].

TR0281: For each element in the MDIB of the SDC BASE PROVIDER, if an optional child element of type pm:LocalizedText corresponds to a label that the SDC BASE PROVIDER can display locally, the SDC BASE PROVIDER SHALL provide that child element with the content of the displayable label either through the LOCALIZATION SERVICE using @Ref or as the element content.

TR0277: For each pm:LocalizedText element with non-empty content that is not defined during use of the SDC BASE PROVIDER, the SDC BASE PROVIDER SHALL include non-empty @Lang.

NOTE—Example of content definition during use: Text that a USER entered to configure part of that SDC BASE PROVIDER, e.g., pm:EnumStringMetricDescriptor/pm:AllowedValue where the pm:Identification/pm:IdentifierName is defined by the USER.

TR0279: In each element that contains one or more pm:LocalizedText elements with non-empty content that is not defined during use of the SDC BASE PROVIDER, the SDC BASE PROVIDER SHALL provide one or more pm:LocalizedText elements with non-empty content and with @Lang being equal to pm:MdsState/@Lang of the containing MDS.

NOTE—Example of content definition during use: Text that a USER entered to configure part of that SDC BASE PROVIDER, e.g., pm:EnumStringMetricDescriptor/pm:AllowedValue where the pm:Identification/pm:IdentifierName is defined by the USER.

6.9 Calibration

IEEE Std 11073-10207 provides the means to express information about the last calibration of a BICEPS CONTAINMENT TREE ENTRY as well as about the next calibration. This section further restricts IEEE Std 11073-10207 by constraining the way an SDC BASE PARTICIPANT has to use these model elements.

TR1451: If an SDC BASE PROVIDER provides information about the last calibration, it SHALL use pm:CalibrationInfo/@ComponentCalibrationState ∈ { No, Cal, Oth }.

NOTE—pm:CalibrationInfo/@ComponentCalibrationState ∈ { Req, Run } are undefined for the last calibration.

TR1453: If an SDC BASE PROVIDER provides information about the next calibration, it SHALL use pm:NextCalibration/@ComponentCalibrationState ∈ { Req, Run, Oth }.

NOTE—pm:NextCalibration/@ComponentCalibrationState ∈ { No, Cal } are undefined for the next calibration.

TR1455: If a particular standard or RISK MANAGEMENT process requires an SDC BASE PROVIDER to indicate the time of the next calibration to the USER, the SDC BASE PROVIDER SHALL provide pm:NextCalibration/@ComponentCalibrationState = Req and non-empty @Time.

7. Conformity

RR0623: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL demonstrate conformity of the SDC BASE PARTICIPANT to every applicable "shall" level requirement defined in this standard.

NOTE—A conditional requirement is applicable if the SDC BASE PARTICIPANT fulfills the parts of the requirement text that constitute conditions (commonly introduced by the complementizers if, while, etc.). In this case, the MANUFACTURER has to demonstrate conformity of the SDC BASE PARTICIPANT to the requirement. Otherwise, the MANUFACTURER has to demonstrate that the SDC BASE PARTICIPANT does not fulfill the conditions.

RR0029: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL demonstrate that every test tool used for conformity testing is verified.

NOTE—This means that a MANUFACTURER demonstrates, e.g., by applying test method validation procedures, that the tool meets its objectives and its intended purpose.

DR1385: The MANUFACTURER of an SDC BASE PARTICIPANT SHALL provide in the ACCOMPANYING INFORMATION specific details about the way that the requirements of this standard have been applied in the form of implementation conformity statements (ICSs).

NOTE 1—An ICS discloses details of a specific implementation and specifies the implemented features and characteristics to support interoperability of applications and systems.

NOTE 2—The ICSs provide understanding of the details of an implementation. However, they are not sufficient to guarantee interoperability of applications or systems. For such interoperability, additional specifications like nomenclatures, device specializations, and "Integrating the Healthcare Enterprise" (IHE) profiles are taken into account. These specifications are out of scope of this standard.

DR1427: For each "should" level requirement that an SDC BASE PARTICIPANT does not satisfy, the MANUFACTURER of the SDC BASE PARTICIPANT SHALL include into the corresponding ICS a rationale as to why the feature was not implemented.

7.1 Implementation conformity statements

7.1.1 General format

Implementation conformity statements take the form of tables. Templates for these ICS tables are given in 7.1.2. The tables are filled out and provided as an overall conformity statement document.

Generally, an ICS table contains the following information:

- Index, which is an identifier of a specific feature;
- Reference, which is a reference to the requirement of the feature;
- Status, which specifies the conformity level, i.e., as to whether the feature is mandatory, recommended, or permissible for a conforming implementation;
- Support, in which the implementer specifies the characteristics of the feature in the implementation; and
- Comment, in which the implementer provides additional information.

The following values of the Status column are permitted:

- **m** (mandatory, indicated by requirement keyword "SHALL")
- **r** (recommended, indicated by requirement keyword "SHOULD")
- **p** (permissible, indicated by requirement keyword "MAY")

The value of the Support column is permitted to range from simple to complex entries. Examples of simple values are:

- **yes** (the requirement is fulfilled)
- **no** (the requirement is not fulfilled)
- **n/a** (the requirement is not applicable, reasons are given in the Comment column)