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Health informatics — Device interoperability —

Part 10701: Point-of-care medical device communication — Metric provisioning by participants in a Service-oriented Device Connectivity (SDC) system

Informatique de santé — Interopérabilité des dispositifs —

Partie 10701: Communication entre dispositifs médicaux sur le site de soins – Fourniture de métriques par les participants à un système de connectivité des dispositifs orientée services (SDC)

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ISO/IEEE 11073-10701 was prepared by the IEEE 11073 Standards Committee of the IEEE Engineering in Medicine and Biology Society (as IEEE Std 11073-10701) and drafted in accordance with its editorial rules. It was adopted, under the "fast-track procedure" defined in the Partner Standards Development Organization cooperation agreement between ISO and IEEE, by Technical Committee ISO/TC 215, *Health informatics*.

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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 defines requirements for SDC metric participants in an SDC system that comprises an IT network of medical devices to enable safe and secure contribution to system functions based on the exchange of metric information.

Keywords: base PKP; BICEPS; communication protocol specification; device component; documentation and process responsibilities; dynamic medical device interoperability; IEEE 11073-10701™; integrated clinical environment; medical device communication; metric; metric PKP; participant key purpose; point-of-care service-oriented device connectivity; risk management; safety, effectiveness, and security; SDC; system function; system function contribution; usability engineering

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Introduction

This introduction is not part of IEEE Std 11073-10701-2022, Health Informatics—Device Interoperability—Part 10701: Point-of-Care Medical Device Communication—Metric Provisioning by 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 METRIC PARTICIPANTs in an SDC SYSTEM that comprises an IT NETWORK of MEDICAL DEVICEs to enable safe and secure contribution to SYSTEM FUNCTIONs based on the exchange of METRIC information.

Examples of such SYSTEM FUNCTIONs are remote display, calculation of derived parameters based on METRIC information, and partial automation of diagnosis and therapy, such as changing settings based on received METRIC information.

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

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Health Informatics—Device Interoperability

Part 10701: Point-of-Care Medical Device Communication—Metric Provisioning by Participants in a Service-Oriented Device Connectivity (SDC) System

1. Overview

1.1 Scope

This standard specifies a set of Participant Key Purposes (PKPs) pertaining to metric data exchange 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*).[1,2]

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).[3] 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.

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

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

[3] Information on references can be found in Clause **Error! Reference source not found.**.

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 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 [B11]).[4] 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, IT 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 METRIC PROVIDER and SDC METRIC CONSUMER PKPs, which comprise requirements regarding METRICs and device components, i.e., CHANNELs, VMDs, and MDSs. Conformity to these PKPs supports safe, effective, and secure exchange of METRIC data between SDC METRIC PARTICIPANTs in an SDC SYSTEM.

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.[5, 6]

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 11073-10700™, 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.

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.[7]

[4] The numbers in brackets correspond to those of the bibliography in Annex F.

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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 [B9])

NOTE 1—The ACCOMPANYING INFORMATION shall be regarded as part of the MEDICAL DEVICE or accessory.[8]

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 [B11])

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

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. (IEEE Std 11073-10700-2022 [B7])

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 [B6]. Its root node is a BICEPS CONTAINMENT TREE ENTRY of the XML Schema type pm:MdsDescriptor. (IEEE Std 11073-10700-2022 [B7])

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. (IEEE Std 11073-10700-2022 [B7])

BICEPS PARTICIPANT: A network node that is part of a SOMDS and exchanges information by providing BICEPS SERVICEs, consuming BICEPS SERVICEs, or both. (IEEE Std 11073-10700-2022 [B7])

BICEPS SERVICE: Interface as specified in the IEEE 11073-10207 Service Model. (IEEE Std 11073-10700-2022 [B7])

BICEPS SERVICE CONSUMER: BICEPS PARTICIPANT that consumes at least one BICEPS SERVICE. (IEEE Std 11073-10700-2022 [B7])

BICEPS SERVICE PROVIDER: BICEPS PARTICIPANT that provides at least one BICEPS SERVICE. (IEEE Std 11073-10700-2022 [B7])

CHANNEL: Abstraction of a logical or physical grouping of METRICs for hierarchical information organization. It corresponds to combinations of pm:ChannelDescriptor and pm:ChannelState. (adapted from IEEE Std 11073-10207-2017 [B6])

NOTE—Definition has been modified by replacing “that allows” with “for” and added “It corresponds to combinations of pm:ChannelDescriptor and pm:ChannelState.”

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

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. (IEEE Std 11073-10700-2022 [B7])

EXTENSION: An element that is a child of an ext:Extension element. (IEEE Std 11073-10700-2022 [B7])

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 [B11])

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 [B11])

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 [B9])

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 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 [B12])

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 [B11])

LABELED CONTAINMENT SUBTREE: A BICEPS CONTAINMENT SUBTREE for whose METRICs an SDC METRIC PROVIDER provides information to be used by an SDC METRIC CONSUMER to compose METRIC labels.

NOTE—The LABELED CONTAINMENT SUBTREE is an optional capability that an SDC METRIC PROVIDER can support.

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 [B6])

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 [B1])

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 [B12])

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. (IEEE Std 11073-10700-2022 [B7])

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

METRIC: Abstraction of a feature of a MEDICAL DEVICE that is able to generate or store direct and derived, quantitative and qualitative biosignal measurements, settings, and status values. This corresponds to combinations of instances of types derived from pm:AbstractMetricDescriptor and pm:AbstractMetricState. (adapted from IEEE Std 11073-10700-2022 [B6])

NOTE—Definition has been modified by replacing “component of a POC MEDICAL DEVICE” with “feature of a MEDICAL DEVICE” and added “This corresponds to combinations of instances of types derived from pm:AbstractMetricDescriptor and pm:AbstractMetricState.”

MODE OF OPERATION: A specific kind of operation of a MEDICAL DEVICE or one of its components that can be active when the device or component is operating.

NOTE 1—A MODE OF OPERATION can typically be activated, paused, or deactivated by the USER or through automated means.

NOTE 2—The MODE OF OPERATION as defined herein is not to be confused with the mode of operation as defined in IEC 60601-1.

OBJECTIVE EVIDENCE: Data supporting the existence or verity of something. (IEC 60601-1:2005/AMD 1:2012/AMD 2:2020 [B1])

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. (IEEE Std 11073-10700-2022 [B7])

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

RESIDUAL RISK: RISK remaining after risk control measures have been implemented. (ISO/IEC Guide 63:2019 [B12])

RISK: Combination of the probability of occurrence of harm and the severity of that harm. (ISO 14971:2019 [B8])

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 [B12])

SDC BASE CONSUMER: BICEPS SERVICE CONSUMER that conforms to the SDC BASE CONSUMER PKP specified in IEEE Std 11073-10700.

SDC BASE PROVIDER: BICEPS SERVICE PROVIDER that conforms to the SDC BASE PROVIDER PKP specified in IEEE Std 11073-10700.

SDC METRIC CONSUMER: An SDC PARTICIPANT KEY PURPOSE that an SDC BASE CONSUMER can assume for consuming METRICs from BICEPS SERVICE PROVIDERs.

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

SDC METRIC PROVIDER: An SDC PARTICIPANT KEY PURPOSE that an SDC BASE PROVIDER can assume for providing METRICs to BICEPS SERVICE CONSUMERs.

SDC PARTICIPANT KEY PURPOSE: A set of requirements that describes a role that a BICEPS PARTICIPANT can play in a SOMDS. (IEEE Std 11073-10700-2022 [B7])

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

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. (IEEE Std 11073-10700-2022 [B7])

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.

SYSTEM FUNCTION: CLINICAL FUNCTION executed by two or more BICEPS PARTICIPANTs that are part of an SDC SYSTEM. (IEEE Std 11073-10700-2022 [B7])

SYSTEM FUNCTION CONTRIBUTION: Function of a BICEPS PARTICIPANT that contributes to a SYSTEM FUNCTION. (IEEE Std 11073-10700-2022 [B7])

SYSTEM FUNCTION USE SPECIFICATION: Section of the USE SPECIFICATION in accordance with IEC 62366-1 [B4] 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. (IEEE Std 11073-10700-2022 [B7])

NOTE—SDC BASE PROVIDERs can declare limitations regarding BICEPS SERVICE CONSUMERs and their configuration for safe and effective use as specified in IEEE Std 11073-10700-2022, R1034 in 5.2.

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 [B11])

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 60601-1:2005/AMD 1:2012/AMD 2:2020 [B1])

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. (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 [B8].

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

ASN.1 Abstract Syntax Notation One

BICEPS Basic Integrated Clinical Environment Protocol Specification

ECG Electrocardiography

ICS Implementation Conformity Statement

IHE Integrating the Healthcare Enterprise

MDIB Medical Data Information Base

MDS MEDICAL DEVICE SYSTEM

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

UI User Interface

XML Extensible Markup Language [B13]

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 METRIC 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 METRIC PARTICIPANT.

Both sections contain requirements towards the documentation of SDC METRIC 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 METRIC 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 11073-10701-2022 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 Definitions [B15]. 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 Namesapces**Error! Reference source not found.**, section 4 [B14]).
- 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

In addition to the XML namespaces defined in IEEE Std 11073-10207, this standard specifies EXTENSIONs that are referenced by means of qualified names. Table 1 provides a mapping of the namespace prefixes that are used throughout this document.

Table 1—Mapping of namespace prefixes used in this standard

Namespace prefix	Namespace	Model part
mpkp	urn:oid:1.3.111.2.11073.10701.3.1.1	EXTENSIONs defined in this standard, see Annex B
ext	Extension model namespace as specified in [IEEE Std 11073-10207]	IEEE 11073-10207 Extension model
pm	Participant model namespace as specified in [IEEE Std 11073-10207]	IEEE 11073-10207 Participant model
msg	Message model namespace as specified in [IEEE Std 11073-10207]	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 C 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 METRIC CONSUMERs and SDC METRIC PROVIDERs.

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

RR0608: The MANUFACTURER of an SDC METRIC PROVIDER SHALL demonstrate conformity of the SDC METRIC PROVIDER to the SDC BASE PROVIDER PKP specified in IEEE Std 11073-10700.

RR0609: The MANUFACTURER of an SDC METRIC CONSUMER SHALL demonstrate conformity of the SDC METRIC CONSUMER to the SDC BASE CONSUMER PKP specified in IEEE Std 11073-10700.

5.2 Intended interoperability

Only the MANUFACTURER of an SDC METRIC CONSUMER knows the SYSTEM FUNCTIONs that the SDC METRIC CONSUMER is intended to execute using the METRICs provided by an SDC METRIC PROVIDER. Therefore, the MANUFACTURER of the SDC METRIC CONSUMER is responsible for all aspects of the SYSTEM FUNCTIONs that are not explicitly allocated to the SDC METRIC PROVIDER.

5.2.1 Responsibilities of the SDC METRIC PROVIDER

The MANUFACTURER of the SDC METRIC PROVIDER cannot be aware of every SYSTEM FUNCTION and clinical benefit that the SDC METRIC PROVIDER can contribute to. Hence, the MANUFACTURER of the SDC METRIC PROVIDER cannot perform a benefit-risk analysis, but can only consider that part of a sequence of events that comprises the provision of its own SYSTEM FUNCTION CONTRIBUTION.

Due to this gap in the knowledge about the sequence of events, the MANUFACTURER of an SDC METRIC PROVIDER assumes that the provision of erroneous information that is marked as valid or validated directly leads to harm. If a METRIC is classified with @SafetyClassification = MedB, the harm is non-serious injury. If a METRIC is classified with @SafetyClassification = MedC, the harm is serious injury or death. This presumed RISK is greater than or equal to the actual RISK of the SYSTEM FUNCTION, which is subject to additional risk control measures implemented by the SDC METRIC CONSUMER.

RR0306: For each of its METRICs with @SafetyClassification = MedA, the MANUFACTURER of an SDC METRIC PROVIDER SHALL consider the causes and contributing factors that result in the provision of erroneous information, assuming that the erroneous information is displayed by an SDC METRIC CONSUMER.

NOTE 1—MedA indicates that the METRIC is intended for display according to the INTENDED USE of the SDC METRIC PROVIDER. This does not imply that the SDC METRIC PROVIDER is necessarily intended to display the METRIC at its own UI.

NOTE 2—Besides technical causes, the MANUFACTURER needs to consider clinical causes and USE ERRORs that result in the provision of erroneous information.

NOTE 3—For the purpose of this requirement, a METRIC with pm:MetricQuality/@Validity ∈ { Qst, Calib, Inv, Oflw, Uflw } is not considered erroneous information.

RR0870: For each of its METRICs with @SafetyClassification = MedB, the MANUFACTURER of an SDC METRIC PROVIDER SHALL consider the causes and contributing factors that result in the provision of erroneous information, assuming that the provision of erroneous information directly leads to non-serious injury.

NOTE 1—Besides technical causes, the MANUFACTURER needs to consider clinical causes and USE ERRORs that result in the provision of erroneous information.

NOTE 2—For the purpose of this requirement, a METRIC with pm:MetricQuality/@Validity ∈ { Qst, Calib, Inv, Oflw, Uflw } is not considered erroneous information.

RR0871: For each of its METRICs with @SafetyClassification = MedC, the MANUFACTURER of an SDC METRIC PROVIDER SHALL consider the causes and contributing factors that result in the provision of erroneous information, assuming that the provision of erroneous information directly leads to serious injury or death.

NOTE 1—This typically entails that the feature represented by the METRIC is designed in a way that a single fault condition does not result in the provision of erroneous information and that the software system is software safety class C as specified in IEC 62304:2006+AMD1:2015 [B3].

NOTE 2—Besides technical causes, the MANUFACTURER needs to consider clinical causes and USE ERRORs that result in the provision of erroneous information.

NOTE 3—For the purpose of this requirement, a METRIC with pm:MetricQuality/@Validity ∈ { Qst, Calib, Inv, Oflw, Uflw } is not considered erroneous information.

5.2.2 Responsibilities of the SDC METRIC CONSUMER

An SDC METRIC CONSUMER has the overall responsibility for a SYSTEM FUNCTION. It is described in the SYSTEM FUNCTION USE SPECIFICATION of the SDC METRIC CONSUMER, which can differ from the USE SPECIFICATION of an SDC METRIC PROVIDER, e.g., in different USER PROFILEs, different USE ENVIRONMENTs, or a different INTENDED USE.

Examples of SYSTEM FUNCTIONs include:

- Combination of multiple METRICs into a score to be displayed by an SDC METRIC CONSUMER,
- Simplification of the range of a METRIC from decimal to enumeration (e.g., color codes),
- A METRIC that is displayed by an SDC METRIC PROVIDER is used for closed-loop control of therapy settings by an SDC METRIC CONSUMER.

When performing the benefit-risk analysis of a SYSTEM FUNCTION, the MANUFACTURER of an SDC METRIC CONSUMER can assume that the MANUFACTURER of the SDC METRIC PROVIDER with which the SDC METRIC CONSUMER executes the SYSTEM FUNCTION, has considered the causes and contributing factors that result in the provision of erroneous information and has implemented risk control measures taking into account the generally acknowledged state of the art.

If METRICs are displayed, the interpretation of the displayed values by the USER is part of the sequence of events. The USER can identify implausible values, e.g., flickering display, distortions, or clinically improbable values. If METRICs are not displayed, e.g., if being interpreted automatically, USERs do not contribute to RISK mitigations.

RR0300: The MANUFACTURER of an SDC METRIC CONSUMER SHALL consider the RISKs that result from using a METRIC of an SDC METRIC PROVIDER in a way that is not covered by the METRIC's @SafetyClassification.

NOTE—This requirement addresses additional RISKs resulting from an SDC METRIC CONSUMER's deviation from the SDC METRIC PROVIDER's @SafetyClassification. All other considerations remain unaffected, esp. relating to the suitability and use of a METRIC for a SYSTEM FUNCTION.

RR0303: The MANUFACTURER of an SDC METRIC CONSUMER SHALL consider the RISKs that result from using a METRIC of a BICEPS SERVICE PROVIDER that does not conform to the SDC METRIC PROVIDER PKP.

NOTE 1—If a BICEPS SERVICE PROVIDER does not conform to the SDC METRIC PROVIDER PKP, the MANUFACTURER of an SDC METRIC CONSUMER cannot assume that the MANUFACTURER of the BICEPS SERVICE PROVIDER has appropriately evaluated and mitigated RISKs related to provided METRICs.

NOTE 2—The SDC METRIC PROVIDER PKP OID is specified in A.2.1.

5.3 System use

RR0307: If an SDC METRIC CONSUMER is intended to display METRICs to USERs and misinterpretation can result in unacceptable RESIDUAL RISK, the MANUFACTURER of the SDC METRIC CONSUMER SHALL provide OBJECTIVE EVIDENCE that its intended USERs can correctly interpret the SDC METRIC CONSUMER's presentation of those METRICs.

NOTE—Examples of RISKs:

- The unit of measure or scaling of waveform is not perceived correctly.
- Time of measurement or timescale is not perceived correctly.
- Inappropriate labels lead to misinterpretation of a METRIC.
- Context information available in SDC, e.g., annotations, device states, or related other METRICs, is not perceived, leading to misinterpretation of a METRIC.
- Correct interpretation of the METRIC requires further context information not provided by SDC, e.g., patient posture or sensor position.
- The USER confuses settings and measurements.

RR0314: If a lack of USER awareness for the source of consumed METRICs can cause unacceptable RISKs, the MANUFACTURER of an SDC METRIC CONSUMER SHALL provide OBJECTIVE EVIDENCE that its intended USERs can identify the source of those METRICs.

NOTE—Examples of RISKs:

- The USER misinterprets METRICs due to insufficient visualization of their source, e.g., an SDC METRIC CONSUMER displays a respiration rate measurement from a monitoring device and a respiration rate setting from a ventilator without sufficient distinction.
- The USER misinterprets METRICs due to insufficient visualization of components, e.g., when an SDC METRIC CONSUMER displays the state multiple syringe pumps with the same medication from one SDC METRIC PROVIDER.
- The USER misinterprets METRICs due to insufficient visualization of the body site, e.g., when an SDC METRIC CONSUMER displays two temperature values, one that represents a patient's core temperature and one that represents the patient's skin temperature.
- The USER confuses METRICs from different patients at an SDC METRIC CONSUMER that allows for the simultaneous display of METRICs from multiple patients.

RR0311: If an SDC METRIC CONSUMER is intended to display METRICs to USERs, the MANUFACTURER of the SDC METRIC CONSUMER SHALL consider the RISKs resulting from USE ERRORs caused by a presentation of METRICs that differs from the potentially unknown presentation at the SDC METRIC PROVIDER.

NOTE 1—Mitigation approaches include, but are not limited to, usability testing of the SDC METRIC CONSUMER, documentation in its INSTRUCTIONS FOR USE, configuration of the SDC METRIC CONSUMER, and training of its USERs.

NOTE 2—Examples of RISKs:

- The USER confuses METRICs due to SDC METRIC PROVIDERs and SDC METRIC CONSUMERs using different color schemes.
- The USER misinterprets METRICs due to SDC METRIC PROVIDERs and SDC METRIC CONSUMERs using different units of measurements. This could be caused by multiple units provided by the SDC METRIC PROVIDER or by a unit conversion performed by the SDC METRIC CONSUMER.

Examples of mitigations:

- The ACCOMPANYING INFORMATION of an SDC METRIC CONSUMER requires the SYSTEM OWNER to configure the display color and display units to correspond to the display of an SDC METRIC PROVIDER.
- The SDC METRIC CONSUMER restricts access to the display configuration to predefined USER GROUPs accountable to the HEALTHCARE DELIVERY ORGANIZATION.

RR0246: If an SDC METRIC CONSUMER is intended to display the @Value or @Samples of an SDC METRIC PROVIDER's METRIC to USERs, the SDC METRIC CONSUMER SHALL consider the RISKs that result from using a display precision that differs from that of the SDC METRIC PROVIDER.

NOTE—If the display precision of the SDC METRIC PROVIDER differs from the currently active pm:Range/@StepWidth, it can be retrieved from the mplp:DisplayPrecision EXTENSION, see TR0242 in 6.1.7.

5.3.1 Quality and timeliness

RR0326: The MANUFACTURER of an SDC METRIC CONSUMER SHALL consider the RISKs that result from using METRICs while they do not have all of the following properties:

- **@SafetyClassification ∈ { MedA, MedB, MedC },**
- **pm:MetricQuality/@Validity ∈ { Vld, Vldated },**
- **pm:MetricQuality/@Mode = Real, and**
- **@ActivationState ∈ { On, StndBy }.**

NOTE—Example of a RISK:

— The USER derives wrong clinical decisions from displayed inaccurate or simulated measurements

Examples of mitigations:

— An SDC METRIC CONSUMER does not display METRICs with @SafetyClassification = Inf.
— An SDC METRIC CONSUMER appropriately marks METRICs with Validity = Qst on its display.
— An SDC METRIC CONSUMER only displays METRICs with @Mode ∈ { Test, Demo } from a BICEPS SERVICE PROVIDER when the SDC METRIC CONSUMER is in test or demo mode as well.

RR0676: The MANUFACTURER of an SDC METRIC CONSUMER SHALL consider the RISKs resulting from the corruption of messages that contain METRICs.

RR0334: The MANUFACTURER of an SDC METRIC CONSUMER SHALL consider the RISKs resulting from the loss of messages that contain METRICs.

NOTE 1—When an SDC METRIC CONSUMER loses or discards a message or parts of a message that contains METRICs, it is no longer able to derive a consistent state of the SDC METRIC PROVIDER.

NOTE 2—An SDC METRIC CONSUMER can use @DescriptorVersion and @StateVersion of the SDC METRIC PROVIDER to detect lost messages and mitigate these RISKs, see IEEE Std 11073-10207-2017, 5.2.5 MDIB versioning [B6].

RR0332: The MANUFACTURER of an SDC METRIC CONSUMER SHALL consider the RISKs resulting from the delay of messages that contain METRICs.

NOTE 1—The reception of a METRIC value is delayed, e.g., by the transmission over an IT NETWORK, measurement duration, or queue congestion.

NOTE 2—The SDC METRIC CONSUMER can use the @DeterminationTime of a METRIC to detect delays.

RR0330: The MANUFACTURER of an SDC METRIC CONSUMER SHALL consider the RISKs that result from using outdated values of METRICs with @MetricCategory ∈ {Msrmt, Clc }.

NOTE 1—A METRIC value is considered outdated when its @LifeTimePeriod has expired or when the SDC METRIC CONSUMER deems it unsuitable for a specific SYSTEM FUNCTION, see RR0322 in 5.3.

NOTE 2—If both an SDC METRIC CONSUMER and an SDC METRIC PROVIDER are synchronized with a time server, the SDC METRIC CONSUMER compares the SDC METRIC PROVIDER's timestamps with its own clock to detect outdated values.

NOTE 3—According to IEEE Std 11073-10700-2022, R1162 in 5.2.2 [B7], the MANUFACTURER of an SDC METRIC CONSUMER is obliged to consider the RISKs resulting from erroneous timestamps.

NOTE 4—Examples of RISKs:

— The USER assumes that a displayed measurement represents the current patient condition although the patient condition has changed after the measurement was taken.

Examples of mitigations:

— An SDC METRIC CONSUMER removes outdated METRICs from its display.
— An SDC METRIC CONSUMER marks outdated METRICs on its display and validates that USERs perceive and understand these marks.

RR0322: For each SYSTEM FUNCTION an SDC METRIC CONSUMER is intended to execute, the MANUFACTURER of the SDC METRIC CONSUMER SHALL consider the RISKs that result from using measured or calculated METRIC values whose @DeterminationTime and @MaxDelayTime indicate that they are not sufficiently recent to be suitable for use in the SYSTEM FUNCTION.

NOTE 1—For a measurement or calculation, the @MaxDelayTime indicates the maximum delay between the actual presence of a value and the @DeterminationTime.

NOTE 2—This requirement addresses RISKs that remain even though the SDC METRIC CONSUMER is aware of the current state of an SDC METRIC PROVIDER. RISKs due to communication delays are addressed by other requirements.

NOTE 3—Example of a RISK:

— The USER assumes that the physiological state of a patient has not changed since the time of the last measurement of a METRIC value.

Examples of mitigations:

— An SDC METRIC CONSUMER displays intermittent METRICs and METRICs that have a long @LifeTimePeriod together with a timestamp.
— An SDC METRIC CONSUMER only uses METRICs for a SYSTEM FUNCTION that have a suitably short @MaxDelayTime.

5.3.2 Label composition

The concept of METRIC modelling as specified in the IEEE Std 11073-10207 standard assumes that the semantic meaning of a METRIC can be derived from its descriptor element and the attribution by its position in the BICEPS CONTAINMENT TREE. One purpose of interpreting the semantic meaning of a METRIC is to provide labeling that allows a USER to identify a METRIC including its source. For example, if a MEDICAL DEVICE provides the same temperature type from multiple METRICs with a different source, the USER usually discriminates between them based on the label that is attached to the METRICs, e.g., T_1, T_2, or T_{ear}.

If an SDC METRIC PROVIDER is intended to supply text for automatic label composition by an SDC METRIC CONSUMER, it can provide a LABELED CONTAINMENT SUBTREE. Indicating this optional capability means that the MANUFACTURER of the SDC METRIC PROVIDER performed additional USABILITY ENGINEERING for composite labels. This supports the USABILITY ENGINEERING of an SDC METRIC CONSUMER that is intended to compose labels from text provided at runtime rather than to use labels of its MANUFACTURER's own design.

RR0602: If an SDC METRIC PROVIDER provides a LABELED CONTAINMENT SUBTREE, for each METRIC that is contained therein, the MANUFACTURER of the SDC METRIC PROVIDER SHALL provide OBJECTIVE EVIDENCE that its intended USERs can understand every label that is composed in the following way:
<label> ::= <type-label> <vmd-label> <channel-label> <metric-label> <bodysite-dlabel> <bodysite-slabel>
where
<type-label> ::= the text of a pm:AbstractMetricDescriptor/pm:Type/pm:ConceptDescription,
<vmd-label> ::= the text of a pm:VmdState/pm:PhysicalConnectorInfo/pm:Label,
<channel-label> ::= the text of a pm:ChannelState/pm:PhysicalConnectorInfo/pm:Label,
<metric-label> ::= the text of a pm:AbstractMetricState/pm:PhysicalConnectorInfo/pm:Label,
<bodysite-dlabel> ::= the text of a pm:AbstractMetricDescriptor/pm:BodySite/pm:ConceptDescription, and
<bodysite-slabel> ::= the text of a pm:AbstractMetricState/pm:BodySite/pm:ConceptDescription,
and where the language is equal.

NOTE 1—The SDC METRIC PROVIDER only verifies that the composed labels are understandable in its own context of use, e.g., they are displayed at a local UI of the SDC METRIC PROVIDER.

NOTE 2—The text of a pm:LocalizedText refers to either the element content or the text retrieved by means of a LOCALIZATION SERVICE.

NOTE 3—The language of a text refers to the pm:LocalizedText/@Lang.

NOTE 4—Evidence has to be provided for every possible combination of those individual texts that are provided. This includes labels composed of elements with different values for attributes such as @TextWidth.

NOTE 5—Not all of these texts have to be provided at all times.

NOTE 6—IEEE Std 11073-10700-2022, R0108 in 6.2 [B7], specifies the mechanism for indicating the LABELED CONTAINMENT SUBTREE capability using the OID defined in A.3.1 of this standard.

There is no guarantee that an SDC METRIC CONSUMER will use an appropriate label unless it has full awareness of the semantic meaning of the METRICs. This requires the SDC METRIC CONSUMER to evaluate the descriptive information, especially the coded types of BICEPS CONTAINMENT TREE ENTRIEs, in order to derive the semantics of the SDC METRIC PROVIDER's capabilities.

RR0604: The MANUFACTURER of an SDC METRIC CONSUMER SHALL consider the RISKs that result from automatically composing labels at runtime and using them at the SDC METRIC CONSUMER's UI.

NOTE 1—Examples of RISKs:

- Labels are misinterpreted when displayed in a different context.
- Labels are not understood by an intended USER GROUP of the SDC METRIC CONSUMER because it is not an intended USER GROUP of the SDC METRIC PROVIDER.

NOTE 2—This requirement applies regardless of whether an SDC METRIC CONSUMER uses the composition schema specified in RR0602 (see 5.3.2) or any other.

6. Technical design

6.1 METRICs

This subclause contains requirements for the provision and consumption of METRICs. Requirements that cover certain topics or that apply only to certain kinds of METRICs have been grouped into subsections for improved readability.

TR0674: While a METRIC's @ActivationState = On, an SDC METRIC PROVIDER SHALL provide the pm:MetricValue element.

TR0399: If either an applicable standard that an SDC METRIC PROVIDER demonstrates conformity to or the RISK MANAGEMENT performed by the MANUFACTURER of the SDC METRIC PROVIDER require indication of a special condition of a value, sample, or a range of samples, the SDC METRIC PROVIDER SHALL provide this indication using pm:MetricValue/pm:Annotation.

NOTE—Example of a required indication: IEC 60601-2-27:2011, Clause 201.12.1.101.12 [B2], requires that if pacemaker pulses are not visible on the display of an ECG monitor, their position shall be indicated by artificially inserted flags.

6.1.1 Units of measurement

TR0866: For each METRIC's @Value or @Samples that the MEDICAL DEVICE represented by an MDS of an SDC METRIC PROVIDER displays to a USER, while the unit of measurement of this display differs from the METRIC's pm:Unit, the SDC METRIC PROVIDER SHALL attach one mpkp:DisplayedBy EXTENSION with @ext:MustUnderstand = false to the METRIC descriptor or state to refer to another METRIC that represents the same feature using the unit of measurement that is displayed to the USER.

NOTE 1—An SDC METRIC PROVIDER can use multiple units of measurement for the same dimension in a single display element, e.g., minutes and seconds for a duration whereas the METRIC's pm:Unit is MDC_DIM_SEC. TR0866 in 6.1.1 applies and can be satisfied by referring to a string METRIC that represents the display element and where pm:Unit conveys the formatting of the string, e.g., one that is defined in ISO 8601 for durations.

NOTE 2—An SDC METRIC PROVIDER can combine two or more METRICs into a single display element, e.g., two METRICs that represent a ratio. If each METRIC's pm:Unit is adequately represented in this display element, TR0866 in 6.1.1 does not apply.

NOTE 3—Depending on the SDC METRIC PROVIDER's UI it can either be more beneficial

- To attach this EXTENSION to the descriptor to avoid sending it at each state update or
- To attach it to the state to avoid descriptor updates when a USER changes the display unit.

6.1.2 METRIC quality

TR0675: While a METRIC's pm:MetricValue/pm:MetricQuality/@Validity ∈ { Vld, Vldated }, an SDC METRIC PROVIDER SHALL provide @Value or @Samples.

TR0081: While the accuracy of a METRIC of an SDC METRIC PROVIDER with @SafetyClassification ∈ { MedA, MedB, MedC } does not meet limits specified either by an applicable standard that the SDC METRIC PROVIDER demonstrates conformity to or in the ACCOMPANYING INFORMATION of the SDC METRIC PROVIDER, the SDC METRIC PROVIDER SHALL set the METRIC's pm:MetricQuality/@Validity = Qst.

NOTE—For example, ISO 80601-2-61:2017, Clause 201.12.1.101 [B10], specifies the SpO2 accuracy limits of pulse oximeter equipment.

IEEE Std 11073-10207 allows for the representation of calibration information that is independent of a METRIC's @Validity. Consequently, providing @ComponentCalibrationState = Run expresses that a calibration is ongoing but does not indicate a change in a METRIC's validity.
If, however, an ongoing calibration causes that correctness of a measured value cannot be verified, IEEE Std 11073-10207-2017, B.61 [B6] requires a BICEPS SERVICE PROVIDER to set the METRIC's @Validity = Calib. Note that the @StartTime of a METRIC value with @Validity = Calib does not indicate the start time of a calibration but the start time of the measurement.

TR0199: While there is one or more METRICs with @Mode ∈ { Demo, Test }, an SDC METRIC PROVIDER SHALL set pm:MdsState/@OperatingMode ∈ { Dmo, Srv, Mtn } of the MDS that contains these METRICs.

TR0262: While an SDC METRIC CONSUMER displays information based on METRICs with @Mode ∈ { Test, Demo }, the SDC METRIC CONSUMER SHALL indicate the @Mode to the USER.

6.1.3 Time attribution

TR0216: While a METRIC's pm:MetricQuality/@Validity = Ong, an SDC METRIC PROVIDER SHALL provide a non-empty @StartTime for this METRIC.

NOTE—@Validity = Ong indicates that a measurement is ongoing.

TR0214: While an SDC METRIC PROVIDER provides @Value or @Samples for a METRIC, the SDC METRIC PROVIDER SHALL also provide @DeterminationTime for that METRIC.

NOTE—@StartTime and @StopTime are not always required, see TR0263.

TR0263: While an SDC METRIC PROVIDER does not provide a pm:AbstractMetricValue/@StartTime or pm:AbstractMetricValue/@StopTime for a METRIC, an SDC METRIC CONSUMER MAY use the METRIC's pm:AbstractMetricValue/@DeterminationTime as their implied value.

6.1.3.1 Continuous METRICs

This clause contains requirements that are specific to METRICs with continuous availability.

TR0187: For each of its METRICs with @MetricAvailability = Cont, an SDC METRIC PROVIDER SHALL NOT set the METRIC's @Validity = Ong.

TR0204: For each of its METRICs with @MetricAvailability = Cont, an SDC METRIC PROVIDER SHALL set a @DeterminationPeriod.

NOTE—If the determination period changes during runtime, the currently active determination period is provided by using pm:AbstractMetricState/@ActiveDeterminationPeriod.

6.1.3.2 Intermittent METRICs

This subclause contains requirements that are specific to METRICs with intermittent availability.

The values of intermittent METRICs can be determined either periodically or episodically. Periodic determination is common for measurements and derived calculations whereas settings and manually entered values are typically determined episodically.

The requirements in this clause specify how to use pm:AbstractMetricDescriptor/@DeterminationPeriod and pm:AbstractMetricState/@ActiveDeterminationPeriod to indicate that a value is determined periodically.

Note that this can differ from the msg:RetrievabilityMethod. IEEE Std 11073-10207-2017 C.88 [B6] recommends to describe the technical retrievability of a METRIC, e.g., msg:RetrievabilityMethod = Per if an event report is sent to subscribers periodically or msg:RetrievabilityMethod = Ep if an event report is sent only upon change.

TR0208: If the value of a METRIC with @MetricAvailability = Intr is determined periodically, an SDC METRIC PROVIDER SHALL provide one or both of pm:AbstractMetricDescriptor/@DeterminationPeriod and pm:AbstractMetricState/@ActiveDeterminationPeriod.

NOTE 1—This implies that while neither @DeterminationPeriod nor @ActiveDeterminationPeriod are provided, the intermittent METRIC is determined episodically.

NOTE 2—According to IEEE Std 11073-10207-2017 5.3.12.2 [B6], pm:AbstractMetricState/@ActiveDeterminationPeriod overrides pm:AbstractMetricDescriptor/@DeterminationPeriod if both are present.

NOTE 3—If the pm:AbstractMetricState/@ActiveDeterminationPeriod of a METRIC with @MetricAvailability = Intr changes during runtime, an SDC METRIC PROVIDER can provide a default value using pm:AbstractMetricDescriptor/@DeterminationPeriod.

TR0573: If periodic determination of the value of a METRIC with @MetricAvailability = Intr can be disabled during runtime, an SDC METRIC PROVIDER SHOULD NOT provide pm:AbstractMetricDescriptor/@DeterminationPeriod.

NOTE—In order to reduce description updates, the MANUFACTURER is advised to only use pm:AbstractMetricState/@ActiveDeterminationPeriod in this particular case.

6.1.4 Measurements and calculations

This subclause contains requirements that are specific to METRICs that represent measurements or calculations.

TR0129: For each METRIC with @MetricCategory ∈ { Msrmt, Clc }, while the METRIC's @ActivationState = StndBy, an SDC METRIC PROVIDER SHALL NOT change the METRIC's @Value or @Samples.

NOTE 1—This does not require the SDC METRIC PROVIDER to knowingly provide invalid data, but it forbids changes to @Value or @Samples while the @ActivationState indicates that the feature represented by the METRIC is not operating. It allows for an SDC METRIC PROVIDER to continue the provision of @Value or @Samples that have been determined before the @ActivationState changed to StndBy.

NOTE 2—According to IEEE Std 11073-10207-2017, 5.4.7 [B6], @Value or @Samples can only be provided while the METRIC's @ActivationState ∈ { On, StndBy }.

TR0210: For each METRIC with @MetricCategory ∈ { Msrmt, Clc } and @SafetyClassification ∈ { MedA, MedB, MedC } with the exception of pm:RealTimeSampleArrayMetricDescriptor, an SDC METRIC PROVIDER SHALL set @LifeTimePeriod in the descriptor or in the state.

NOTE 1—If the lifetime period changes during runtime, a default value can be provided in the descriptor whereas the currently active lifetime period is provided in the state.

NOTE 2—A @DeterminationPeriod that is shorter than the @LifeTimePeriod decreases the likelihood that an SDC METRIC CONSUMER is left without a useful value.

TR0682: For each METRIC with @MetricCategory ∈ { Msrmt, Clc } and @SafetyClassification ∈ { MedA, MedB, MedC }, an SDC METRIC PROVIDER SHALL set @MaxDelayTime.

6.1.4.1 Measurement status indication and notification

TR0231: If an SDC METRIC PROVIDER provides a METRIC with @MetricAvailability = Intr and @MetricCategory = Msrmt, it MAY also provide a pm:AlertConditionDescriptor where

- **pm:Source references this METRIC,**
- **pm:Type/@Code = MDC_EVT_STAT_MSMT_START, and**
- **@Priority = None;**

and a pm:AlertSignalDescriptor where

- **pm:Type/@Code = MDC_ATTR_ALERT_INDICATION and**
- **@ConditionSignaled refers to the pm:AlertConditionDescriptor**

that indicate, when present, the initiation of a measurement.

NOTE—If this indication is used for different measurements of the same SDC METRIC PROVIDER, the pm:AlertConditionDescriptor/pm:Source can reference more than one METRIC.

TR0232: If an SDC METRIC PROVIDER provides a METRIC with @MetricAvailability = Intr and @MetricCategory = Msrmt, it MAY also provide a pm:AlertConditionDescriptor where

- **pm:Source references this METRIC,**
- **pm:Type/@Code = MDC_EVT_STAT_MSMT_COMPLETE, and**
- **@Priority = None;**

and a pm:AlertSignalDescriptor where

- **pm:Type/@Code = MDC_ATTR_ALERT_INDICATION and**
- **@ConditionSignaled refers to the pm:AlertConditionDescriptor**

that indicate, when present, the completion of a measurement.

NOTE—If this indication is used for different measurements of the same SDC METRIC PROVIDER, the pm:AlertConditionDescriptor/pm:Source can reference more than one METRIC.

TR0577: If an SDC METRIC PROVIDER provides a METRIC with @MetricAvailability = Intr and @MetricCategory = Msrmt, it MAY also provide a pm:AlertConditionDescriptor where

- **pm:Source references this METRIC and**
- **pm:Type/@Code = MDC_EVT_STAT_MSMT_ABORTED,**

and a pm:AlertSignalDescriptor where

- **pm:Type/@Code = MDC_ATTR_ALERT_INDICATION and**
- **@ConditionSignaled refers to the pm:AlertConditionDescriptor**

that indicate, when present, that a measurement was aborted before a value could be obtained.

NOTE 1—If this indication is used for different measurements of the same SDC METRIC PROVIDER, the pm:AlertConditionDescriptor/pm:Source can reference more than one METRIC.

NOTE 2—Depending on the METRIC type, the cancellation of an ongoing measurement can be a severe event. In contrast to TR0231 and TR0232 in 6.1.4.1, which specify advisory signals, this requirement does not specify an alert condition @Priority to allow for the MANUFACTURER of the SDC METRIC PROVIDER to choose an appropriate alert condition @Priority depending on the severity of the cancellation.

TR0578: If an SDC METRIC PROVIDER provides a METRIC with @MetricAvailability = Intr and @MetricCategory = Msrmt, it MAY also provide a pm:AlertConditionDescriptor where

- **pm:Source references this METRIC and**

— **pm:Type/@Code = MDC_EVT_STAT_MSMT_FAILED,**

and a pm:AlertSignalDescriptor where

— **pm:Type/@Code = MDC_ATTR_ALERT_INDICATION and**
— **@ConditionSignaled refers to the pm:AlertConditionDescriptor**

that indicate, when present, that a measurement failed before a value could be obtained.

NOTE 1—If this indication is used for different measurements of the same SDC METRIC PROVIDER, the pm:AlertConditionDescriptor/pm:Source can reference more than one METRIC.

NOTE 2—Depending on the METRIC type, the failure of an ongoing measurement can be a severe event. In contrast to TR0231 and TR0232 in 6.1.4.1, which specify advisory signals, this requirement does not specify an alert condition @Priority to allow for the MANUFACTURER of the SDC METRIC PROVIDER to choose an appropriate alert condition @Priority depending on the severity of the failure.

6.1.5 Settings and presets

This subclause contains requirements that are specific to METRICs that represent settings or presets.

TR0136: For all of its METRICs with @MetricCategory ∈ { Set, Preset }, an SDC METRIC PROVIDER SHALL set the METRIC's @MetricAvailability = Intr.

NOTE—Settings and presets can be updated continuously, e.g., during closed-loop control, but they are still considered intermittent, because there is not necessarily a periodicity that is under the SDC METRIC PROVIDER's control.

TR0128: For all of its METRICs with @MetricCategory ∈ { Set, Preset }, while the METRIC's @ActivationState ∈ { On, StndBy }, an SDC METRIC PROVIDER SHALL provide @Value or @Samples.

TR0658: If an SDC METRIC PROVIDER provides a METRIC with @MetricCategory = Preset that is a preset for a METRIC with @MetricCategory = Set, the SDC METRIC PROVIDER SHALL set the same pm:Type/@Code, @CodingSystem, and @CodingSystemVersion for both METRICs.

TR0659: If an SDC METRIC PROVIDER provides a METRIC with @MetricCategory = Preset that is a preset for a METRIC with @MetricCategory = Set and is contained in a different CHANNEL, the SDC METRIC PROVIDER SHALL set the preset's pm:Relation/@Kind = PS and pm:Relation/@Entries referring to the setting it is a preset for.

TR0660: If an SDC METRIC PROVIDER provides a METRIC with @MetricCategory = Preset that is a preset for a METRIC with @MetricCategory = Set and there exists another METRIC with @MetricCategory = Set that has the same pm:Type and that is contained in the same CHANNEL, the SDC METRIC PROVIDER SHALL set the preset's pm:Relation/@Kind = PS and pm:Relation/@Entries referring to the setting it is a preset for.

TR0657: While an SDC METRIC PROVIDER pauses the application of a value to a METRIC with @MetricCategory = Set and the application of this value can be resumed, the SDC METRIC PROVIDER SHOULD provide this value in a METRIC with @MetricCategory = Preset.

6.1.6 Enumerations

This subclause contains requirements that are specific to enumeration string METRICs.

TR0487: For each pm:EnumStringMetricDescriptor of an SDC METRIC PROVIDER, for each instance of pm:AllowedValue, the SDC METRIC PROVIDER SHALL provide a pm:Value that is unique within the scope of the pm:EnumStringMetricDescriptor.

NOTE—The semantic concept of an allowed value is conveyed by pm:EnumStringMetricDescriptor/pm:AllowedValue/pm:Type within the context of the enclosing pm:EnumStringMetricDescriptor/pm:Type.

6.1.7 Ranges

This subclause contains requirements that are specific to numeric and sample array METRICs.

TR0239: For each of its numeric and sample array METRICs, an SDC METRIC PROVIDER SHALL provide one or more pm:TechnicalRange elements including an @Upper and @Lower limit.

TR0800: For each METRIC of an SDC METRIC PROVIDER, for each pm:Range of the METRIC, while the minimum numerical distance between two values differs from the METRIC's @Resolution, the SDC METRIC PROVIDER SHOULD provide this distance using pm:Range/@StepWidth.

TR0242: For each METRIC's @Value or @Samples that the MEDICAL DEVICE represented by an MDS of an SDC METRIC PROVIDER displays to a USER, while the precision of this display differs from the METRIC's @Resolution or the active pm:Range has a @StepWidth that differs from the METRIC's @Resolution, the SDC METRIC PROVIDER SHALL provide the display precision by attaching one mpkp:DisplayPrecision EXTENSION with @ext:MustUnderstand = false to the active pm:Range element.

NOTE—The mpkp:DisplayPrecision/@StepWidth implies the number of decimal places that are used on display. For example, a value of 0.1 or 0.4 indicates that one decimal place is displayed whereas a value of 4 or 20 indicates that no decimal place is displayed.

6.2 Device components

TR1075: While a pm:ChannelState/@ActivationState = Off, for each METRIC of that CHANNEL, an SDC METRIC PROVIDER SHALL set pm:AbstractMetricState/@ActivationState = Off.

6.2.1 MODEs OF OPERATION of a device or component

To facilitate consistent modelling across different SDC METRIC PROVIDERs, this clause provides the following guidelines for representing MODEs OF OPERATION.

A MODE OF OPERATION can be exclusive, i.e., only one of a given set of modes can be active at any point in time. Examples include the type of a high frequency (HF) surgical mode that describes the operator-selectable output characteristics of HF surgical equipment.

A MODE OF OPERATION can also be non-exclusive, i.e., it can be active in parallel with other modes. Examples include adjunct ventilation modes or intermittent vital signs measuring modes.

Exclusive and non-exclusive MODEs OF OPERATION can be combined. For example, there could be one or more main modes with only one being active at any given point in time and zero or more adjunct modes for each main mode, where some logic can exist that allows only a subset of the adjunct modes to be active in parallel for each main mode.

In addition to being fully deactivated, some MODEs OF OPERATION can be paused. This facilitates, for example, resuming the activation of a MODE OF OPERATION that represents a process instead of starting this process anew.

TR0482: An SDC METRIC PROVIDER SHALL represent MODEs OF OPERATION as METRICs of the type pm:EnumStringMetricDescriptor.

TR0478: An SDC METRIC PROVIDER SHOULD represent exclusive MODEs OF OPERATION as a METRIC of the type pm:EnumStringMetricDescriptor where the instances of pm:AllowedValue use pm:Type to semantically describes the MODEs OF OPERATION that are available.

TR0252: An SDC METRIC PROVIDER SHOULD represent each non-exclusive MODE OF OPERATION as a METRIC of the type pm:EnumStringMetricDescriptor whose pm:Type semantically describes the MODE OF OPERATION and where the instances of pm:AllowedValue have the pm:Type of:

- **MDC_MODE_OF_OPERATION_ON,**
- **MDC_MODE_OF_OPERATION_OFF, and**
- **optionally MDC_MODE_OF_OPERATION_PAUSED.**

NOTE—The appropriate metric activation state is to be applied according to IEEE Std 11073-10207.

TR0960: For each METRIC representing an adjunct MODE OF OPERATION that depends on a main MODE OF OPERATION, an SDC METRIC PROVIDER SHOULD provide a pm:Relation where @Entries refer to the METRIC that represents the main MODE OF OPERATION.

To indicate the duration for which a MODE OF OPERATION is going to be active, the SDC METRIC PROVIDER uses @ActivationDuration. Due to the definition of the @ActivationDuration in IEEE Std 11073-10207 that is tied to the METRIC's @ActivationState, the SDC METRIC PROVIDER needs to change pm:MetricValue and @ActivationState simultaneously at the end of @ActivationDuration.

In this particular case, "active" therefore refers to both the pm:ActivationState = On and the pm:MetricValue corresponding to the pm:AllowedValue with pm:Type/@Code = MDC_MODE_OF_OPERATION_ON.

TR0256: If an SDC METRIC PROVIDER sets an active MODE OF OPERATION to MDC_MODE_OF_OPERATION_OFF or MDC_MODE_OF_OPERATION_PAUSED after a certain period of time, the SDC METRIC PROVIDER SHALL specify this period of active application using the @ActivationDuration of the METRIC that represents that MODE OF OPERATION.

TR1009: If an SDC METRIC PROVIDER sets an active MODE OF OPERATION to MDC_MODE_OF_OPERATION_OFF or MDC_MODE_OF_OPERATION_PAUSED after a certain period of time, the SDC METRIC PROVIDER SHALL also set the METRIC's pm:ActivationState to any state other than On after this period.

TR0257: For a METRIC that represents a MODE OF OPERATION with @Value = MDC_MODE_OF_OPERATION_ON and with an @ActivationDuration, an SDC METRIC CONSUMER MAY determine the latest point in time at which the MODE OF OPERATION is going to be deactivated by adding the @ActivationDuration to the @DeterminationTime.

6.2.2 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.

TR0219: For any two or more METRICs with @MetricCategory ∈ { Msrmt, Clc, Set, Unspec } where @MetricCategory is equal and where pm:Type, pm:Unit, pm:AbstractMetricDescriptor/pm:BodySite, and pm:AbstractMetricState/pm:BodySite are semantically equivalent, an SDC METRIC PROVIDER SHALL provide one or more of

- **<mds-label> ::= the text of a pm:MdsState/pm:PhysicalConnectorInfo/pm:Label,**
- **<vmd-label> ::= the text of a pm:VmdState/pm:PhysicalConnectorInfo/pm:Label,**
- **<channel-label> ::= the text of a pm:ChannelState/pm:PhysicalConnectorInfo/pm:Label, and**
- **<metric-label> ::= the text of a pm:MetricState/pm:PhysicalConnectorInfo/pm:Label**

such that for each of these METRICs every concatenation <mds-label> <vmd-label> <channel-label> <metric-label> with equal @Lang is unique among these METRICs.

NOTE 1—An SDC METRIC PROVIDER only provides individual labels, but no concatenations.

NOTE 2—The text of a pm:Label refers to either the element content or the text retrieved by means of a LOCALIZATION SERVICE.

NOTE 3—Every possible combination of those individual texts that are provided has to be unique. This includes concatenations of elements with different values for attributes such as @TextWidth.

NOTE 4—Examples of labels:

- The string representation of the attribute pm:PhysicalConnectorInfo/@Number
- A more descriptive label like “Aux 3”

— Annex E exemplifies a METRIC label composition scheme.

7. Conformity

RR0502: The MANUFACTURER of an SDC METRIC PARTICIPANT SHALL demonstrate conformity of the SDC METRIC PARTICIPANT to every applicable “shall” level requirement defined in this standard.

NOTE—A conditional requirement is applicable if the SDC METRIC 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 METRIC PARTICIPANT to the requirement. Otherwise, the MANUFACTURER has to demonstrate that the SDC METRIC PARTICIPANT does not fulfill the conditions.

DR0503: The MANUFACTURER of an SDC METRIC 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.

DR0505: For each “should” level requirement that an SDC METRIC PARTICIPANT does not satisfy, the MANUFACTURER of the SDC METRIC 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)

7.1.2 Tables

Table 2—ICSs applicable to all SDC METRIC PARTICIPANTs

Index	Reference	Status	Support	Comment
ICS-502	RR0502	m		
ICS-503	DR0503	m		
ICS-505	DR0505	m		

Table 3—ICSs applicable only to SDC METRIC PROVIDERs

Index	Reference	Status	Support	Comment
ICS-608	RR0608	m		
ICS-306	RR0306	m		
ICS-870	RR0870	m		
ICS-871	RR0871	m		
ICS-674	TR0674	m		
ICS-399	TR0399	m		
ICS-866	TR0866	m		
ICS-675	TR0675	m		
ICS-81	TR0081	m		
ICS-199	TR0199	m		
ICS-216	TR0216	m		
ICS-214	TR0214	m		
ICS-187	TR0187	m		
ICS-204	TR0204	m		
ICS-208	TR0208	m		
ICS-573	TR0573	r		
ICS-129	TR0129	m		
ICS-210	TR0210	m		
ICS-682	TR0682	m		
ICS-231	TR0231	p		
ICS-232	TR0232	p		
ICS-577	TR0577	p		
ICS-578	TR0578	p		
ICS-136	TR0136	m		
ICS-128	TR0128	m		
ICS-658	TR0658	m		
ICS-659	TR0659	m		
ICS-660	TR0660	m		
ICS-657	TR0657	r		
ICS-487	TR0487	m		
ICS-239	TR0239	m		
ICS-800	TR0800	r		
ICS-242	TR0242	m		
ICS-1075	TR1075	m		
ICS-482	TR0482	m		
ICS-478	TR0478	r		
ICS-252	TR0252	r		
ICS-960	TR0960	r		
ICS-256	TR0256	m		
ICS-1009	TR1009	m		
ICS-219	TR0219	m		

Table 4—ICSs applicable only to SDC METRIC CONSUMERs

Index	Reference	Status	Support	Comment
ICS-609	RR0609	m		
ICS-300	RR0300	m		
ICS-303	RR0303	m		
ICS-307	RR0307	m		
ICS-314	RR0314	m		
ICS-311	RR0311	m		
ICS-246	RR0246	m		
ICS-326	RR0326	m		
ICS-676	RR0676	m		
ICS-334	RR0334	m		
ICS-332	RR0332	m		
ICS-330	RR0330	m		
ICS-322	RR0322	m		
ICS-604	RR0604	m		
ICS-262	TR0262	m		
ICS-263	TR0263	p		
ICS-257	TR0257	p		

Annex A

(normative)

Object Identifiers

This normative annex defines Object Identifiers (OIDs) that are used as unique, stable, and versioned references for different information items. It provides Object Identifiers assigned under the IEEE 11073 OID arc.

A.1 OID assignments

Table A.1 specifies the Object Identifiers for conformity concepts defined in this standard.

Table A.1—OID assignments

Primary identifier	Concept description	Secondary identifier
1.3.111.2.11073.10701	Part 10701: Point-of-Care Medical Device Communication -- Metric Provisioning by Participants in a Service-Oriented Device Connectivity (SDC) System	part10701
1.3.111.2.11073.10701.0	Versions of IEEE 11073-10701	versions
1.3.111.2.11073.10701.0.1	IEEE 11073-10701-2022	version1
1.3.111.2.11073.10701.1	Metric Participant Key Purpose Conformity	mpkp-conformity
1.3.111.2.11073.10701.1.1	Conformity to SDC METRIC PROVIDER PKP	metric-provider
1.3.111.2.11073.10701.1.1.1	Version 1 of the SDC METRIC PROVIDER PKP	version1
1.3.111.2.11073.10701.1.2	Conformity to SDC METRIC CONSUMER PKP	metric-consumer
1.3.111.2.11073.10701.1.2.1	Version 1 of the SDC METRIC CONSUMER PKP	version1
1.3.111.2.11073.10701.2	Conformity to additional requirements	additional-conformity
1.3.111.2.11073.10701.2.1	Conformity to LABELED CONTAINMENT SUBTREE requirements	label-provider
1.3.111.2.11073.10701.2.1.1	Version 1 of the LABELED CONTAINMENT SUBTREE requirements	version1
1.3.111.2.11073.10701.3	Namespaces	namespaces
1.3.111.2.11073.10701.3.1	EXTENSION namespace	extension
1.3.111.2.11073.10701.3.1.1	Version 1 of the EXTENSION namespace	version1

Every OID starts with 1.3.111.2.11073, which translates to the ASN.1 notation {iso(1) identified-organization(3) ieee(111) standards-association-numbered-series-standards(2) ieee11073(11073)}. The number 10701 references this standard; it is followed by sub-arcs referring to particular concepts, which have an individual version number.

Example: {iso(1) identified-organization(3) ieee(111) standards-association-numbered-series-standards(2) ieee11073(11073) part10701(10701) mpkp-conformity(1) metric-consumer(2) version1(1)}

A.2 Participant Key Purpose concept definitions

A.2.1 Conformity to SDC METRIC PROVIDER PKP

The OID 1.3.111.2.11073.10701.1.1.1 designates conformity to all mandatory requirements for an SDC METRIC PROVIDER as specified in this version of this standard.

A.2.2 Conformity to SDC METRIC CONSUMER PKP

The OID 1.3.111.2.11073.10701.1.2.1 designates conformity to all mandatory requirements for an SDC METRIC CONSUMER as specified in this version of this standard.