

DIN EN ISO 11073-20101

ICS 35.100.70; 35.240.80

**Medizinische Informatik –
Kommunikation patientennaher medizinischer Geräte –
Teil 20101: Anwendungsprofil – Basisnorm
(ISO/IEEE 11073-20101:2004);
Englische Fassung EN ISO 11073-20101:2005**

Health informatics –
Point-of-care medical device communication –
Part 20101: Application profiles – Base standard (ISO/IEEE 11073-20101:2004);
English version EN ISO 11073-20101:2005

Informatique de santé –
Communication entre dispositifs médicaux sur le site des soins –
Partie 20101: Profils d'applications – Norme de base (ISO/IEEE 11073-20101:2004);
Version anglaise EN ISO 11073-20101:2005

Gesamtumfang 86 Seiten

Normenausschuss Medizin (NAMed) im DIN

Nationales Vorwort

Diese Norm enthält unter Berücksichtigung des Präsidialbeschlusses 13/1998 den englischen Originaltext der Europäischen Norm EN ISO/IEEE 11073-20101:2005. Die Europäische Norm wurde in der WG IV „Technology for Interoperability“ des CEN/TC 251 „Medizinische Informatik“ übernommen und im Rahmen eines gemeinsamen Projektes zwischen ISO und IEEE erarbeitet. Der NA 063-07-02 AA „Interoperabilität“ des Fachbereichs 7 „Medizinische Informatik“ des Normenausschusses Medizin im DIN hat an der Erarbeitung mitgewirkt.

Für die im Abschnitt 2 zitierten Internationalen Normen wird im Folgenden auf die entsprechenden Deutschen Normen hingewiesen:

ISO/IEEE 11073-10101	siehe DIN EN ISO 11073-10101
ISO/IEEE 11073-10201	siehe DIN EN ISO 11073-10201
ISO/IEEE 11073-30200	siehe DIN EN ISO 11073-30200
ISO/IEEE 11073-30300	siehe DIN EN ISO 11073-30300

Zusammenfassung

Die ISO/IEEE11073-Standardfamilie ermöglicht die Datenübertragung zwischen Medizingeräten und Computersystemen. Sie erlaubt die automatisierte, detaillierte Erfassung von patientenbezogenen Vitaldaten und Funktionsparametern durch die Verwendung von Überwachungs- und Therapiegeräten — beispielsweise auf einer Intensivstation oder im Operationssaal. Die primären Ziele dabei sind:

- Bereitstellung von „Plug-and-Play“-Funktionalität und Interoperabilität mit Patienten verbundener Medizingeräte für Realzeitanwendungen.
- Vereinfachung des effizienten Austausches gemessener Vitaldaten von Patienten und Betriebsdaten der verwendeten Medizingeräte.

„Echtzeit“ bedeutet, dass Daten von mehreren Medizingeräten zeitgenau erfasst und in Bruchteilen von Sekunden dargestellt oder verarbeitet werden können, werden können. „Plug and Play“ beinhaltet, dass eine medizinische Fachkraft lediglich die Verbindung zum Gerät herstellen muss, worauf das System automatisch — ohne weiteren menschlichen Eingriff — das neu angeschlossene Medizingerät erkennt, Kommunikationsparameter sowie gegebenenfalls die Applikation konfiguriert und danach die Kommunikation von Daten aufnimmt.

Diese Norm stellt für die ISO/IEEE 11073-Standardfamilie abstrakte Syntax und Transfersyntax (d. h. Kodierregeln) bereit, die für die Verwendung durch Anwendungsprofile und Implementierungen des Domänen-Informationsmodells optimiert sind.

Folgende Annahmen und Anforderungen hinsichtlich Kommunikationsstack und zugeordneter Protokolldefinitionen gelten für diese Basisnorm und abgeleitete Profile:

- Während der Kommunikationsstack soweit möglich auf bereits existierenden Standards aufbaut, steht für die Protokolldefinition die Gesamteffizienz möglicher Implementierungen (z. B. hinsichtlich Komplexität, Ressourcen- bzw. Bandbreitenanforderungen) im Vordergrund. Insbesondere müssen Implementierungen eines auf dieser Norm basierenden Kommunikationsstacks auch für „Low-end“-Geräte möglich sein.

- Um Sende- und Empfangsaufwand zu vermindern, sollten die von jeder Protokollschicht hinzugefügten Nachrichtenköpfe kurz sein und eine feste Datenstruktur ohne optionale Elemente oder solche variabler Länge aufweisen. Dadurch ist es sendenden Geräten möglich, vorformulierte Nachrichten zu verwenden, die in den Arbeitsspeicher kopiert werden und in die dort lediglich die aktuell zu übertragenden Datenwerte eingesetzt werden müssen. Empfängerseitig reduziert dies die Komplexität des Parsers beträchtlich. Im gleichen Zusammenhang steht die Notwendigkeit optimierter Kodierregeln.
- Es gilt die Annahme, dass für die Kommunikation medizinischer Geräte kein komplexes Protokoll der Sitzungsschicht (ISO/OSI-Ebene 6) erforderlich ist, insbesondere, da einige Fehlerbehandlungsmechanismen bereits für Objekte der Anwendungsschicht definiert sind (z. B. Scanner-Objekt in ISO/IEEE 11073-10201).

Die normative Definition von Benutzerschnittstellen ist nicht Gegenstand dieser Norm.

Nationaler Anhang NA (informativ)

Literaturhinweise

DIN EN ISO 11073-10101:2006-09, *Medizinische Informatik – Kommunikation patientennaher medizinischer Geräte – Teil 10101: Nomenklatur (ISO/IEEE 11073-10101:2004); Englische Fassung EN ISO 11073-10101:2005*

DIN EN ISO 11073-10201:2006-09, *Medizinische Informatik – Kommunikation patientennaher medizinischer Geräte – Teil 10201: Bereichs-Informationsmodell (ISO/IEEE 11073-10201:2004); Englische Fassung EN ISO 11073-10201:2005*

DIN EN ISO 11073-30200:2006-09, *Medizinische Informatik – Kommunikation patientennaher medizinischer Geräte – Teil 30200: Transportprofil - drahtgebundene Übertragung (ISO/IEEE 11073-30200:2004); Englische Fassung EN ISO 11073-30200:2005*

DIN EN ISO 11073-30300:2006-09, *Medizinische Informatik – Kommunikation patientennaher medizinischer Geräte – Teil 30300: Transportprofil – drahtlose Infrarotübertragung (ISO/IEEE 11073-30300:2004); Englische Fassung EN ISO 11073-30300:2005*

— Leerseite —

English Version

Health informatics - Point-of-care medical device communication -
Part 20101: Application profiles - Base standard
(ISO/IEEE 11073-20101:2004)

Informatique de santé - Communication entre dispositifs
médicaux sur le site des soins - Partie 20101: Profils
d'applications - Norme de base
(ISO/IEEE 11073-20101:2004)

Medizinische Informatik - Kommunikation patientennaher
medizinischer Geräte - Teil 20101: Anwendungsprofil -
Basisnorm (ISO/IEEE 11073-20101:2004)

This European Standard was approved by CEN on 16 August 2005.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

Contents

Foreword	4
1. Overview.....	5
1.1 Scope.....	6
1.2 Purpose.....	6
1.3 Goals	6
1.4 Audience	6
2. References.....	6
3. Definitions and abbreviations	8
3.1 Definitions	8
3.2 Acronyms and abbreviations	8
4. Conventions	10
5. Rationale	10
5.1 Communication model.....	10
5.2 Information model	11
6. Communication model.....	12
6.1 General.....	12
6.2 ACSE protocol	14
6.2.1 General.....	14
6.2.2 ACSE services	14
6.2.3 ACSE ASN.1 message definition	16
6.2.4 ACSE user information fields.....	16
6.3 Session-layer protocol.....	16
6.3.1 General.....	16
6.3.2 Session-layer services	16
6.3.3 Session-layer message definitions	17
6.4 Presentation-layer protocol	17
6.4.1 General.....	17
6.4.2 Presentation-layer services	18
6.4.3 Presentation-layer messages	18
6.5 ROSE protocol	18
6.5.1 General.....	18
6.5.2 ROSE services	18
6.5.3 ROSE message definitions.....	18
6.6 CMDISE protocol (CMDIP).....	19
6.6.1 General.....	19
6.6.2 CMDISE services	19
6.6.3 CMDIP message definitions	19
6.6.4 SNTP.....	19
7. Information model	20
7.1 Object model.....	20
7.2 Format model.....	20

7.2.1 Syntax 20

7.2.2 Compatibility 20

8. Conformance..... 21

8.1 Scope..... 21

8.2 Object identifier administration 21

8.3 MDAP subset conformance 21

8.4 Implementation conformance 21

Annex A (normative) Medical device encoding rules (MDER)..... 22

Annex B (normative) Allocation of identifiers..... 33

Annex C (informative) Time synchronization..... 36

Annex D (informative) Dynamic model..... 37

Annex E (normative) Abstract syntax 42

Annex F (informative) PDU examples 63

Annex G (informative) Specialization of ASN.1..... 76

Annex H (informative) Compatibility cases..... 79

Annex I (informative) Bibliography 81

Foreword

The text of ISO/IEEE 11073-20101:2004 has been prepared by Technical Committee ISO/TC 215 “Health informatics” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 11073-20101:2005 by Technical Committee CEN/TC 251 “Health informatics”, the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2006, and conflicting national standards shall be withdrawn at the latest by February 2006.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

Endorsement notice

The text of ISO/IEEE 11073-20101:2004 has been approved by CEN as EN ISO 11073-20101:2005 without any modifications.

1. Overview

This standard is divided into eight clauses, as follows:

- Clause 1 provides the scope of this standard.
- Clause 2 lists references to other standards that are useful in applying this standard.
- Clause 3 provides definitions and abbreviations.
- Clause 4 provides conventions.
- Clause 5 provides the rationale for this standard.
- Clause 6 provides a communication, i.e., protocol and service, model.
- Clause 7 provides an information, i.e., object, model.
- Clause 8 provides conformance requirements.

This standard also contains nine annexes, as follows:

- Annex A defines the specialized medical device encoding rules (MDER). (normative)
- Annex B describes the allocation of object identifiers. (normative)
- Annex C provides references to time synchronization protocols applied by this standard.
- Annex D includes state transition diagrams as part of the dynamic model.
- Annex E provides abstract syntax, which offers extensions to leveraged standards, such as minimal open systems interconnection (mOSI), that are specific to this standard. (normative)
- Annex F includes examples of a number of protocol data unit (PDU) examples.
- Annex G describes a specialization of Abstract Syntax Notation One (ASN.1).
- Annex H deals with compatibility of ASN.1 between the 1988/90 and 1994 versions.
- Annex I provides a bibliography of useful references.

1.1 Scope

The scope of this standard is upper layer [i.e., the International Organization for Standardization's (ISO's) open systems interconnection (OSI) application, presentation layer, and session layer] services and protocols for information exchange under the ISO/IEEE 11073 standards for medical device communications (MDC).

This standard is the base standard of the ISO/IEEE 11073-20000 medical device application profiles (MDAP), as harmonized through the Committee for European Normalization (CEN) and the ISO.

1.2 Purpose

The purpose of this standard is to define MDC upper layer application, i.e., ISO A-type profiles for interchange of data, which are defined by the medical device data language (MDDL) format, or ISO F-type profiles (ISO/IEEE 11073-10000 series).

1.3 Goals

The primary goal of MDAP standards is to support MDC upper layer data interchange, based on MDDL, among a wide range, by type and scale, of future and current devices for use in point-of-care (POC) settings in the acute care sections of hospitals.

1.4 Audience

The primary user of the MDAP standards is a software engineer who is creating a MDC system or attempting to establish an interface to one.

Because this family of standards is based largely upon international standardization profiles, familiarity with a range of related standards and technologies is useful if not necessary. The following are recommended as a minimum background:

- a) ISO/IEEE 11073 architecture, especially IEEE Std 1073^{TM,1}, ISO/IEEE 11073-10201, and lower layer standards (e.g., ISO/IEEE 11073-30200)
- b) ISO's OSI layered architecture, primarily the upper layers, i.e., application, presentation, and session
- c) Systems management
- d) Object-oriented analysis and design
- e) Machine language theory

2. References

This standard shall be used in conjunction with the following publications. When the following standards are superseded by an approved revision, the revision shall apply.

IEEE Std 1073, IEEE Standard for Medical Device Communications—Overview and Framework.²

¹Information on references can be found in Clause 2.

²IEEE publications are available from the Institute of Electrical and Electronics Engineers, Inc., 445 Hoes Lane, Piscataway, NJ 08854, USA (<http://standards.ieee.org/>).

ISO/IEC 8327-1, Information technology — Open systems interconnection — Connection-oriented session protocol — Part 1: Protocol specification.³ (same as ITU-T Recommendation X.225)

ISO/IEC 8650-1, Information technology — Open systems interconnection — Connection-oriented protocol for the association control service element — Part 1: Protocol. (same as ITU-T Recommendation X.227)

ISO/IEC 8824-1, Information technology — Abstract Syntax Notation One (ASN.1) — Part 1: Specification of basic notation. (same as ITU-T Recommendation X.680)

ISO/IEC 8824-2, Information technology — Abstract Syntax Notation One (ASN.1) — Part 2: Information object specification. (same as ITU-T Recommendation X.681)

ISO/IEC 8825-1, Information technology — ASN.1 encoding rules — Part 1: Specification of Basic Encoding Rules (BER), Canonical Encoding Rules (CER) and Distinguished Encoding Rules (DER). (same as ITU-T Recommendation X.690)

ISO/IEC 9072-2, Information processing systems — Text communication — Remote operations — Part 2: Protocol specification.

ISO/IEC 9595, Information technology — Open systems interconnection — Common management information service definition.

ISO/IEC 9596-1, Information technology — Open systems interconnecton — Common Management Information Protocol — Part 1: Specification.

ISO/IEC 9899, Programming languages — C.

ISO/IEC ISP 11188-3, Information technology — International standardization profile — Common upper layer requirements — Part 3: Minimal OSI upper layer facilities.

ISO/IEEE 11073-10101, Health informatics — Point-of-care medical device communication — Part 10101: Nomenclature.⁴

ISO/IEEE 11073-10201, Health informatics — Point-of-care medical device communication — Part 10201: Domain information model (referred to hereinafter as “the DIM”).

ISO/IEEE 11073-30200, Health informatics — Point-of-care medical device communication — Part 30200: Transport profile — Cable connected.

ISO/IEEE 11073-30300, Health informatics — Point-of-care medical device communication — Part 30300: Transport profile — Infrared Wireless.

ITU-T Recommendation X.681, Information Technology—Abstract Syntax Notation One (ASN.1)—Information Object Specification. (same as ISO/IEC 8824-2)⁵

³ISO/IEC publications are available from the ISO Central Secretariat, Case Postale 56, 1 rue de Varembé, CH-1211, Genève 20, Switzerland/Suisse (<http://www.iso.ch/>). ISO/IEC publications are also available in the United States from Global Engineering Documents, 15 Inverness Way East, Englewood, CO 80112, USA (<http://global.ihs.com/>). Electronic copies are available in the United States from the American National Standards Institute, 25 West 43rd Street, 4th Floor, New York, NY 10036, USA (<http://www ansi.org/>).

⁴ISO/IEEE publications are available from the ISO Central Secretariat, Case Postale 56, 1 rue de Varembé, CH-1211, Genève 20, Switzerland/Suisse (<http://www.iso.ch/>); in the United States from the Sales Department, American National Standards Institute, 25 West 43rd Street, 4th Floor, New York, NY 10036, USA (<http://www.ansi.org/>); and from the Institute of Electrical and Electronics Engineers, Inc., 445 Hoes Lane, Piscataway, NJ 08854, USA (<http://standards.ieee.org/>).

⁵ITU-T publications are available from the International Telecommunications Union, Place des Nations, CH-1211, Geneva 20, Switzerland/Suisse (<http://www.itu.int/>).

3. Definitions and abbreviations

3.1 Definitions

For the purposes of this standard, the following terms and definitions apply. IEEE 100, *The Authoritative Dictionary of IEEE Standards Terms and Definitions*, Seventh Edition [B3],⁶ should be referenced for terms not defined in this clause.

3.1.1 abstract syntax: Specification of the structure of a data item without reference to or requirement for a specific implementation technology.

3.1.2 big endian: A byte order sequence where the most significant byte is sent first. For example, a 32 bit integer is communicated with the most significant byte (bits 24–31) first and the least significant byte (bits 0–7) last.

3.1.3 byte order: The sequence in which multibyte data primitives are communicated in a protocol data unit (PDU). For example, a 32 bit integer comprises 4 bytes. *See also:* **big endian**.

3.1.4 coalescing: The function of combining multiple presentation-layer protocol data units (PPDUs) into a single session-layer protocol data unit (SPDU) that is then communicated across a transport.

3.1.5 encoding rules: Specification for how data primitives used in an abstract syntax are converted to an implementation format. Generally synonymous with transfer syntax.

3.1.6 linked reply: A command response that requires more than one protocol data unit (PDU) to communicate information. For example, a single command to retrieve an entire log file may result in many linked response PDUs to provide the requested information.⁷

3.1.7 presentation data value (PDV): The union of the sets of values in all possible abstract syntaxes.

3.1.8 transfer syntax: Specification of the structure of data as they are communicated across a transport or physical medium.

3.2 Acronyms and abbreviations

The following acronyms and abbreviations supplement the acronyms and abbreviations of IEEE Std 1073:

AA	(session) abort accept (SPDU)
AARE	association response message
AARQ	association request message
AB	(session) abort (SPDU)
ABRT	abort (APDU)
AC	(session) accept (SPDU)
ACSE	association control service element
AE	application entity
AP	application process
APDU	application protocol data unit

⁶The numbers in brackets correspond to the numbers of the bibliography in Annex I.

⁷A *linked command* definition and service have been omitted from this version of the standard. This command requires multiple PDUs to convey the needed information. For example, a command to send a list of drug names to a device may require multiple linked PDUs. This command may be added to future versions of the standard if required by other profile and optional package standards.

API	application program interface
ARP	abnormal release provider (PPDU)
ARU	abnormal release user (PPDU)
ASN.1	Abstract Syntax Notation One
BCC	bedside communication controller
BER	basic encoding rules
CC	communication controller
CMDIP	Common Medical Device Information Protocol
CMIP	Common Management Information Protocol
CMISE	common management information service element
CMDISE	common medical device information service element
CN	(session) connect (SPDU)
CP	connect presentation (PPDU)
CPA	connect presentation accept (PPDU)
CPR	connect presentation reject (PPDU)
DCC	device communication controller
DICOM	Digital Imaging and Communications in Medicine
DIF	device interface
DIM	domain information model (see ISO/IEEE 11073-10201.)
DN	(session) disconnect (SPDU)
DT	(session) data transfer (SPDU)
FN	(session) finish (SPDU)
FSM	finite state model or machine
LI	length indicator
LSB	least significant bit
MDAP	medical device application profiles (The acronym <i>MDAP</i> may be substituted for the ISO/IEEE 11073-20000 family of standards.)
MMDAP-DT	medical device application profiles normal data transfer (SPDU)
MMDAP-TD	medical device application profiles transmit data (PPDU)
MDAP-XT	medical device application profiles expedited data transfer (SPDU)
MDC	medical device communications or the nomenclature for such communication (ISO-IEEE 11073-10101)
MDCC	medical device communication controller
MDDL	medical device data language (The acronym <i>MDDL</i> may be substituted for the ISO/IEEE 11073-10000 family of standards.)
MDER	medical device encoding rules
MDIB	medical data information base
MDNF	medical device numeric format
MDS	medical device system
MDSE	medical device service element
MIB	management information base
mOSI	minimal open systems interconnection
MSB	most significant bit
MTU	maximum transfer unit
NBO	network byte order
OSI	open systems interconnection

PDU	protocol data unit (also referred to as a <i>message</i> ; however, <i>PDU</i> connotes transfer through a transport profile, e.g., ISO/IEEE 11073-30200).
PDV	presentation data value
PER	packed encoding rules
PGI	parameter group identifier
PI	parameter identifier
POC	point of care or point-of-care
PPDU	presentation-layer protocol data unit
QoS	quality of service
RF	(session) refuse (SPDU)
ROER	remote operation error (APDU)
ROIV	remote operation invoke (APDU)
ROLIV	remote operation link invoke (APDU)
RORS	remote operation result (APDU)
ROSE	remote operation service element
SI	SPDU identifier
SNTP	Simple Network Time Protocol
SPDU	session-layer protocol data unit
SS	session service
TD	presentation data (PPDU)
UML	unified modeling language

4. Conventions

Various definitions use prefixed or suffixed symbols to denote specialized or optimized properties. An asterisk (*) is appended to some definitions to indicate specialization. For example, BER* refers to a version of basic encoding rules (BER) that has been significantly optimized for processing efficiency.

5. Rationale

The essential requirement for this standard is to provide a set of abstract and transfer (i.e., encoding rule) syntaxes that are optimized for use by application profiles and implementations of the domain information model (DIM).

5.1 Communication model

The following assumptions and requirements are for the base standard and profiles of it regarding the communication stack and related protocol definitions:

- While the communication stack should be based on already existing standards as far as possible, a primary focus for the protocol definition is on the overall efficiency of implementations (e.g., complexity, resource requirements, bandwidth requirements). It is necessary that even low-end devices be capable of implementing a communication stack based on this work.
- In order to reduce sending and receiving overhead, the headers added by each layer should, therefore, be short and have a fixed data structure without optional or variable size elements.

By avoiding optional components or variable length components in the PDU data type definitions, it is possible for sending devices to use canned messages (in other words, a message template can be

filled in memory in which only the actual updated values must be copied). Also, for the receiver, this significantly reduces the complexity of the parser.

This requirement is also strongly related to the requirement for optimized encoding rules.

- The communication stack should be flexible so that other messaging profiles can be accommodated within the same framework.

The protocol stack is defined by PDU (data) type definitions and dynamic behavior only. The normative definition of application programming interfaces (APIs) is outside the scope of this standard; however, non-normative examples may be given to facilitate implementation and reuse.

It is desirable to define a transport-independent interface, although specific mappings of upper layer PDUs to services of an ISO/IEEE 11073-30000 transport profile is addressed through transport-specific sublayers as necessary.

General mechanisms at the transport interface to make provisions for information and behavior related to quality of service (QoS) may be considered.

It is assumed that no complicated session-layer protocol is needed for the communication between medical devices, especially as some error recovery mechanisms are actually defined by application objects defined in MDDL (e.g., scanner objects).

However, to support the standard association control service element (ACSE), a minimal set of ISO/OSI standard session services (SSs) is needed at least during association.

In addition, specific session-layer extensions need to be defined to optimize session-layer processing during normal communication (after association) that can coexist with the session-layer protocol defined in ISO/IEC 8327-1.

These optimizations relate, for example, to

- Simplification of the normal session-layer PDU (SPDU)
- Coalescing of application data in single SPDUs to reduce the message rate at the transport interface and below

5.2 Information model

The following assumptions and requirements regard the communication controller (CC) object model:

- Similar to the objects defined in the MDDL, objects defined in this model represent information that is shared between devices through the communication link. The objects defined here are part of the device medical data information base (MDIB) (directly or indirectly accessible), and they are basically information containers.
- The object model will focus on generalized concepts for the representation of communication interface capabilities (ranging, for example, from link speeds to general QoS-related parameters), interface configuration aspects and statistical data (e.g., for troubleshooting). The model should be independent of specific lower layer implementations, but may contain adaptations specific to IEEE lower layers.
- The medical device communication controller (MDCC) inherits from medical device data language (MDDL) CC, as defined in MDDL.1 (IEEE Std 1073.3.1TM [B5]); definitions may be replicated for clarity and reference convenience in this standard.
- Unified modeling language (UML) is to be used as a notation.

Object attributes and behavior will be defined in a notation that is consistent with the MDDL standard, in particular

- Static views: inheritance, containment, attribution
- Dynamic views
 - The device connection state machine with all message interchanges
 - Object-specific dynamic behavior, e.g., for scanner objects defined in MDDL

Dynamic modeling is necessary to define the actual interactions between communicating medical devices.

In addition, information objects pertaining to management information need to be defined to facilitate support, for example, of configuration, access, performance, and fault tolerance information as defined in ISO/IEEE 11073-30200.

6. Communication model

This clause is intended to include service and protocol definitions.

6.1 General

Figure 1 shows the upper layer communication stack, i.e., the layered set of protocol and service components.

The figure shows the components of the communication stack, as follows:

- ACSE is the ISO/OSI standard for association control.
A standard association mechanism provides the flexibility to adopt future requirements, e.g., additional format profiles in the upper layers (such as picture formats and Simple Network Time Protocol [SNTP]), different encoding mechanisms.
It also provides a safe and secure compatibility check and some limited means for option negotiation (e.g., to make sure that both devices use compatible nomenclature versions).
- Common medical device information service element (CMDISE) is the object management service, in principle, a lightweight version of the ISO/OSI common management information service element (CMISE).
- The remote operation service element (ROSE) provides basic services used by the CMDISE (invoke an operation, return the result of an operation, return an error, reject an operation). To comply with the definition of optimized encoding rules, a modified version of the ROSE is needed to work with the CMDISE.
- The session layer and presentation layer produce a minimized overhead only.
- Medical device service element (MDSE) is the overall set of these elements. Encapsulation permits transparency and implementation flexibility in that applications do not have to know about the internal composition of the MDSE, and implementers can choose to integrate specific elements in various ways as long as the interfaces to the application processes and transport system result in a conforming implementation.

Components of the MDIB are defined normatively in the DIM and management information base (MIB) elements documents and are summarized briefly as follows:

- Medical device system (MDS): the highest level containment object representing the device overall.
- CC: a general object from which specializations are defined, as follows:
 - Device CC (DCC): a specialization representing the device CC agent.

- Bedside CC (BCC): a specialization representing a DCC manager (i.e., host CC).
- Device interface (DIF): an abstraction representing a transport service access point.
- MIB element: an abstraction representing performance, status, or other related information. Specialized MIB elements are particular to a given DIF configuration or implementation.

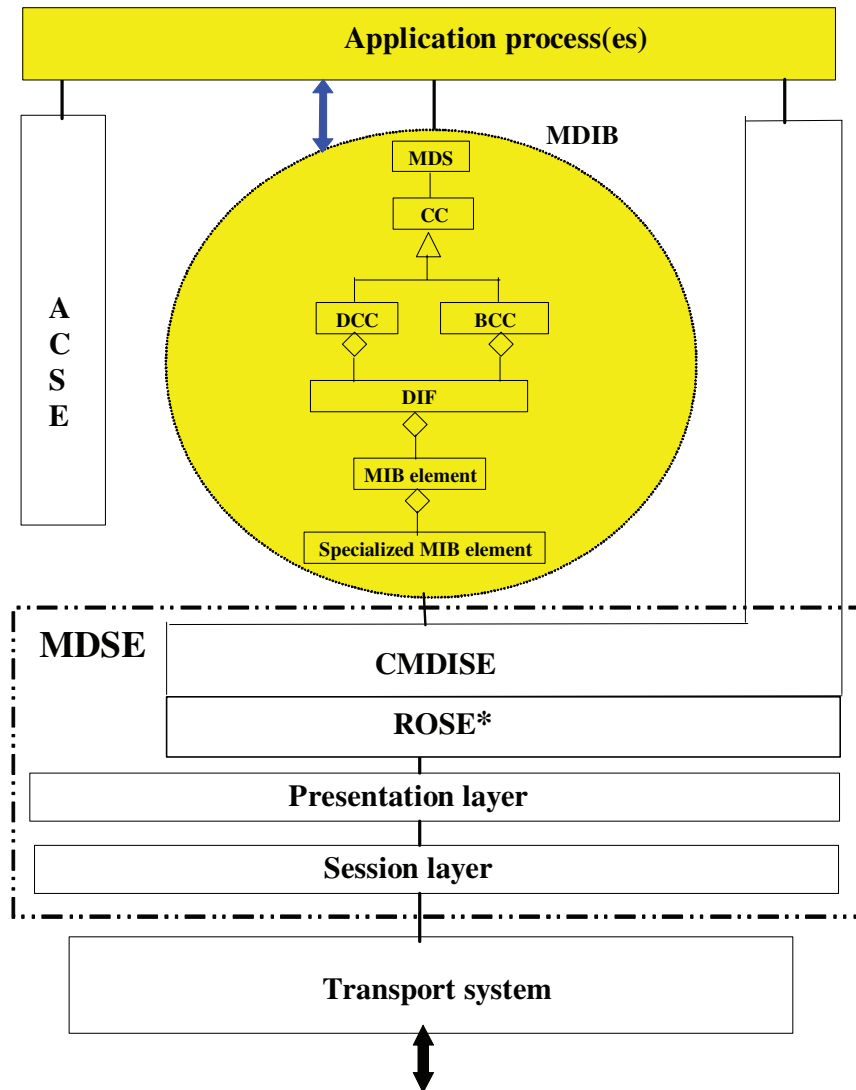


Figure 1—MDC stack

An application message, such as an event report message from a scanner object as defined in MDDL, flows through this communication stack as shown in Figure 2.

The scanner retrieves data from the MDIB and wraps it in a scanner event information field.

After that, each layer (or stack element) copies the data portion and wraps it in its own PDU message, typically by adding some layer-specific header data.

The receiving system reverses this process: Each layer strips the wrapper and header information and passes the result to the next level.

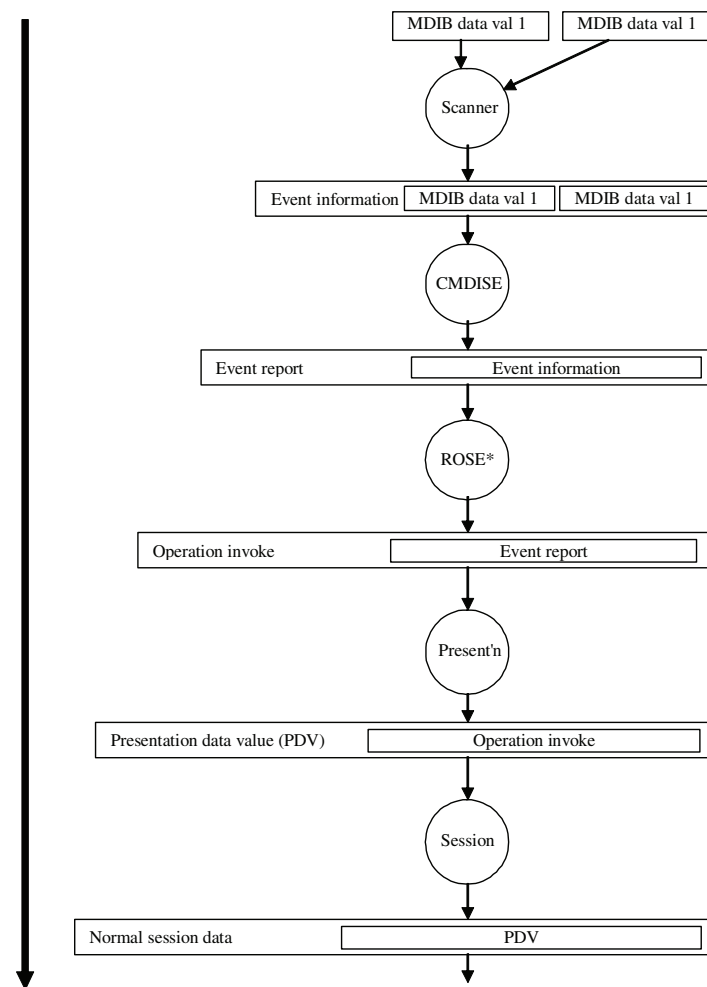


Figure 2—Data flow through the communication stack

6.2 ACSE protocol

6.2.1 General

For association control, it is assumed that the standard ACSE as defined in ISO/IEC 8650-1 is used.

In addition to the standard ACSE, it is necessary to define the set of application-specific user information fields as well as the minimum (and mandatory) set of optional elements in the standard ACSE PDUs.

6.2.2 ACSE services

Table 1 shows the services provided by ACSE.

The services are mapped to messages, i.e., application PDUs (APDUs). For the A-ASSOCIATE services, for example, there are two messages: the association request message (AARQ) and the association response message (AARE).

Table 1—ACSE service summary

Service	Type
A-ASSOCIATE	Confirmed
A-RELEASE	Confirmed
A-ABORT	Nonconfirmed
A-P-ABORT	Provider-initiated

Each service (and thus the resulting APDU) has a number of data fields or parameters. Table 2 and Table 3 show the actual parameters of the AARQ and AARE service calls that are defined in ACSE. The fields are indicated as M for mandatory, O for optional, or U for user optional.

Table 2—AARQ APDU fields

Field name	Presence
Protocol version	O
Application context name	M
Calling application process (AP) title	U
Calling application entity (AE) qualifier	U
Calling AP invocation-identifier	U
Calling AE invocation-identifier	U
Called AP title	U
Called AE qualifier	U
Called AP invocation-identifier	U
Called AE invocation-identifier	U
Implementation information	O
User information	U

Table 3—AARE APDU fields

Field name	Presence
Protocol version	O
Application context name	M
Responding AP title	U
Responding AE qualifier	U
Responding AP invocation-identifier	U
Responding AE invocation-identifier	U

Table 3—AARE APDU fields (continued)

Field name	Presence
Result	M
Result source—diagnostic	M
Implementation information	O
User information	U

As can be seen, the majority of the fields are optional. Only a very small set is mandatory.

The ACSE in the interoperability profile is only a vehicle for a standardized connection setup. Additional information, supplied in the user information field, is defined in this standard to facilitate medical device interoperability.

6.2.3 ACSE ASN.1 message definition

Refer to Annex E for detailed definition.

For true interoperability, ACSE messages shall be BER encoded. Furthermore, they shall be wrapped in the corresponding presentation-layer PDU (PPDU) (CP: Connect Presentation, CPA: Connect Presentation Accept) and SPDU (CN: Session Connect, AC: Session Accept), as defined in Annex E.

6.2.4 ACSE user information fields

The user-specific (i.e., application-specific) information fields in the ACSE message definition for use in the inter-operability communication stack are defined in Annex E.

For startup, only minimal information needs to be supplied in the ACSE PDUs. After the association phase, all other necessary data for application and compatibility checking can be supplied in native CMDISE services using definitions from MDDL.

6.3 Session-layer protocol

6.3.1 General

6.3.2 Session-layer services

The session-layer protocol defines a set of services used for connection and data transfer. Important services to be considered here are

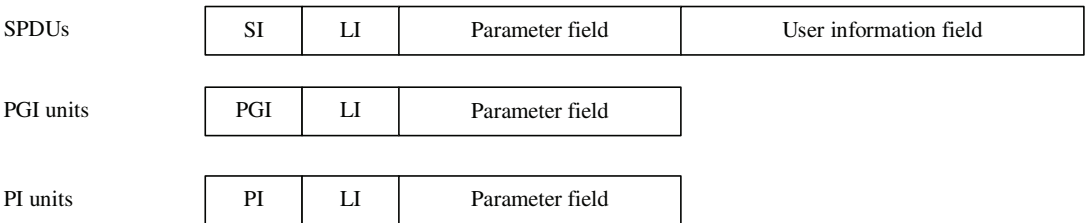
- Session connect
- Session accept
- Session data transfer

A number of additional services and PDUs may be relevant. This needs to be further investigated, especially regarding the mapping between ACSE, PPDU, and SPDU.

6.3.3 Session-layer message definitions

For all needed standard SSs as well as for the optimized session-layer extension, the PDU structure (session header) will be defined.

SPDUs are constructed from simpler elements in the form shown in Figure 3.



LEGEND

- LI: length indicator (length 0-254: one octet; otherwise, 3 octets with first being 255)
- PGI: parameter group identifier (defines a group of session-layer parameters)
- PI: parameter identifier (defines a single session-layer parameter)
- SI: SPDU identifier (unique identifier that defines the session-layer message type)

Figure 3—SPDU format

The parameter fields are constructed from PGI and PI units with certain rules (in accordance with ISO/IEC 8327-1).

An example of a session-layer message is given in 6.3.3.1.

6.3.3.1 Session connect (CN) SPDU

The format and contents of the CN SPDU are as follows:

0D XX	SI=13 (CN), LI = length in octets
05 06	PGI=05(connect/accept item), LI=06
13 01 00	PI=19 (options), LI=1, value = 0
16 01 03	PI=22 (version), LI=1, value = 3
14 02 00 02	PI=20 (user requirements), LI=2, value: select full duplex functional unit
C1 YY	PGI=193 (user data), LI= length of user data

6.4 Presentation-layer protocol

6.4.1 General

In general, the presentation-layer protocol allows negotiating the abstract syntax (e.g., MDDL over CMDISE ASN.1) and transfer syntax (i.e., optimized encoding rules, e.g., MDER) between systems.

As for the session-layer protocol, some limited standard services are necessary to support the ACSE.

The major added value of the presentation layer is the syntax negotiation during association. Also, it allows the definition of multiplex points (presentation context identifiers) in the application, which in turn allows

the communication of data in different formats within the same association [e.g., Digital Imaging and Communications in Medicine (DICOM) images]. In a given association, it is possible to support multiple presentation contexts simultaneously.

For the normal communication between medical devices (after association), the processing and messaging requirements for the presentation layer should be as small as possible.

6.4.2 Presentation-layer services

The presentation layer provides, for example, the following services:

- Connect presentation
- Connect presentation accept
- Presentation data

6.4.3 Presentation-layer messages

Refer to Annex E for definition of the following PDUs:

- Connect presentation (CP) PPDU
- Connect presentation accept (CPA) PPDU
- Connect presentation reject (CPR) PPDU
- Abnormal release provider (ARP) PPDU
- Abnormal release user (ARU) PPDU
- Presentation data (TD) PPDU

6.5 ROSE protocol

6.5.1 General

The ROSE is used by the Common Medical Device Information Protocol (CMDIP). It provides a linkage between invoke messages and result messages (i.e., requests and responses) by means of invoke identifier fields. It also contains a field to distinguish the various remote operations (here: CMDISE services).

The ROSE protocol uses the same abstract syntax that is negotiated for the CMDIP and the data structures from ISO/IEEE 11073-10201. As a result, modifications to the ISO/OSI ROSE are needed to comply with the restrictions of optimized ASN.1 encoding rules.

6.5.2 ROSE services

The ROSE protocol is a relatively simple protocol defining the following services:

- Remote operation invoke
- Remote operation result
- Remote operation error
- Remote operation reject

6.5.3 ROSE message definitions

Refer to Annex E for ROSE PDU definitions.

6.6 CMDISE protocol (CMDIP)

6.6.1 General

6.6.2 CMDISE services

The following basic services may be provided by MDAPs, depending on scalability (i.e., minimum, basic, and extended profiles have different requirements):

- Retrieve object attribute value
- Modify object attribute value
- Invoke object defined functions
- Create and delete object instances
- Report events that occurred within an object

Parameters for each of the services and the related results are defined in the MDDL. Table 4 gives an example for the event report service:

Table 4—Event report service parameters

Parameter	Description
Invoke identifier	Unique identifier (e.g., a sequence number) assigned to a specific instance of the service so that it can be distinguished from other service invocations that a service provider may have in progress.
Mode	Confirmed or unconfirmed; confirmed mode requires a response
Object class	Identifies class of the object that generates the event (values defined in nomenclature or dictionary)
Object instance	Identifies instance of the object that generates the event
Event time	Time the event was generated
Event type	Identifies the type of the event (values defined in nomenclature or dictionary)
Event information	(Optional) additional information about the event, as defined by the event type parameter; the event information is defined by the object that generates the event

6.6.3 CMDIP message definitions

ASN.1 data type definitions for all CMDIP services are defined in Annex E.

Note that some CMDISE service parameters defined in MDDL may actually map to ROSE. In particular the invoke identifier and mode parameters are really defined in the ROSE, as explained in 6.5.

Refer to Annex E for PDU examples.

6.6.4 SNTF

Refer to Annex C.

7. Information model

7.1 Object model

This subclause is intended to include object class definitions, which in general include the following classes.

- CC, e.g., DCC, BCC
- MIB

Refer to the DIM for definition detail.

7.2 Format model

7.2.1 Syntax

7.2.1.1 Transfer syntax

Transfer syntax are defined in Annex A.

Mappings to ISO ASN.1 may be found in Annex G.

7.2.1.2 Abstract syntax

Abstract syntax is defined in Annex E.

7.2.2 Compatibility

In general, it is desirable to maintain syntactical backwards-compatibility, especially for transfer syntax, although such compatibility is not always possible. This subclause is intended to identify significant compatibility issues and resolution to facilitate implementation. Refer to Table 5.

Table 5—Compatibility cases

Case	Issue	Resolution
1	Compatibility of 1988/90 and 1994 versions of ISO ASN.1 and related encoding rules (ISO/IEC 8824 series, ISO/IEC 8825 series)	
1.1	ANY DEFINED BY changed; refer to Annex H for background information.	<ol style="list-style-type: none"> 1. ABSTRACT SYNTAX: Modules shall follow guidelines in ISO/IEC 8824-1; see Annex H. 2. TRANSFER SYNTAX: MDER for ANY DEFINED BY or instance-of type shall be identical; see Annex A.

8. Conformance

This clause is intended to define conformance criteria.

8.1 Scope

To maximize implementation flexibility and interoperability, implementation conformance scope in this base standard is limited to protocols. However, application profiles may define service definitions, as appropriate.

8.2 Object identifier administration

This standard allocates object identifier administration authority to other standards, especially MDDL. Administration authority requires referencing of the MDAP arc and then specification of the extensions allocated by the extensive standard.

8.3 MDAP subset conformance

MDAP profiles shall specify the extent of conformance with this standard by exception categories, as follows:

- a) *No exceptions:* The subset takes no exceptions to this standard.
- b) *Some exceptions:* The subset takes some exceptions to this standard. In this case only the specific exceptions require specification. In the event that this standard defines a table for conformance specification, the subset standard shall replicate the table and fill in the specific cases of conformance for all cases, whether conforming or not.

8.4 Implementation conformance

Device implementers may not specify conformance with this standard, but must specify conformance with a profile that references this standard. As noted in 8.1, implementation conformance shall be limited to protocols, although informative, definitions of APIs are appropriate to facilitate reuse of implementation components.

Annex A

(normative)

Medical device encoding rules (MDER)

A.1 General

This annex defines specialized MDER, which concerns presentation of sequential binary strings as they are intended to appear on the network relative to organization in computer memory, to representation in abstract syntax, i.e., programming language or abstract syntax, or to diagrams that are used in specifications. This specification is intended to be consistent with respect to any and all ISO/IEEE 11073 lower layer alternatives; thus, implementations in the upper layers may have to provide for transparency based on a specific lower layer profile.

Significant goals for MDER include the ability to optimize formatting and parsing performance as well as minimizing bandwidth utilization. Formatting optimization focuses on the ability of a data communication processor to define so-called *canned* messages in which only dynamically changing data need to be included in relatively high-frequency messages, particularly waves.

A.2 Supported ASN.1 syntax

ASN.1 is a standard notation that is used for the definition of data types, values, and constraints on values. This notation is used extensively in OSI standards and is used extensively in the ISO/IEEE 11073 family of standards (e.g., in ISO/IEEE 11073-10201 where all the data definitions are formalized using ASN.1).

In order to support the requirement for encoding and decoding performance and support of canned messages, the MDER defines methods to transform ASN.1 syntax into a byte stream suitable for communication.

In contrast to other ISO/OSI standards for ASN.1 encoding rules (e.g., BER, packed encoding rules [PER]) MDER is optimized for a subset of the ASN.1 only. MDER does not support the full set of ASN.1 data types, but only a defined, restricted set of ASN.1 constructs.

The ISO/IEEE 11073 family of standards uses this restricted set of ASN.1 for the definition of data types used within the managed medical objects only, so MDER is suitable and sufficient for the encoding of data structures within these standards.

The restricted set of ASN.1 used for ISO/IEEE 11073 PDU components is a strict subset of legal ASN.1 data types, so other general standard encoding rules (e.g., BER, PER) can be used as well, as negotiated in the specific upper layers communication profile.

Table A.1 defines the specialization of ASN.1 suitable for encoding with MDER. All ASN.1 PDU components destined for encoding with MDER are subject to this specialization.

For each ASN.1 data type, this specialization is indicated by I for included with restriction, R for restrictions on use, or E for excluded.

Refer to Annex H for further details on specialization of ASN.1 types in MDER.