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Medical Devices and Medical Systems — Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model

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Foreword

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ASTM shall not be held responsible for identifying any or all such patent rights.

ASTM 2761 was prepared by ASTM Committee F-29, *Anaesthetic and Respiratory Equipment*, Subcommittee 21, *Devices in the integrated clinical environment*. This work is based in part on concepts developed within the CIMIT Program [8] on Interoperability and the Massachusetts General Hospital program on Medical Device "Plug-and-Play" Interoperability ("MD PnP" program, founded 2004) with information disseminated through publications, workshops, and website. [9] [28],[37]

This is the first edition.

ASTM 2761 is expected to part of a series of standards, under the general title Medical Devices and Medical Systems — Essential principles of safety and performance for equipment comprising the patient-centric integrated clinical environment (ICE):

— *ASTM F-2761, Medical Devices and Medical Systems — Essential principles of safety and performance for equipment comprising the patient-centric integrated clinical environment (ICE) Part 1: General requirements and conceptual model (this standard)*

— *ASTM F-----, Medical Devices and Medical Systems — Essential principles of safety and performance for equipment comprising the patient-centric integrated clinical environment (ICE) Part 2: Requirements for network control and equipment interface*

— *ASTM F-----, Medical Devices and Medical Systems — Essential principles of safety and performance for equipment comprising the patient-centric integrated clinical environment (ICE) Part 3: Requirements for device models*

— *ASTM F-----, Medical Devices and Medical Systems — Essential principles of safety and performance for equipment comprising the patient-centric integrated clinical environment (ICE) Part 4: Requirements for supervision*

— *ASTM F-----, Medical Devices and Medical Systems — Essential principles of safety and performance for equipment comprising the patient-centric integrated clinical environment (ICE) Part 5: Requirements for safe and reliable integration*

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN THIS STANDARD OR AS NOTED: SMALL CAPS.

In this standard, the conjunctive "or" is used as an "inclusive or" so a statement is true if any combination of the conditions is true.

For the purposes of this standard, the auxiliary verb:

- “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

- “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

- “may” is used to describe a permissible way to achieve compliance with a requirement or test.

Clauses, subclauses and definitions for which a rationale is provided in informative Annex A are marked with an asterisk (*).

NOTE Attention is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication not be adopted for mandatory implementation nationally earlier than 3 years from the date of publication for equipment newly designed and not earlier than 5 years from the date of publication for equipment already in production.

Introduction

MEDICAL DEVICES are essential for the practice of modern medicine. Some MEDICAL DEVICES utilize open networking standards for communication to provide data for the electronic health record. However, unlike the interoperable "plug-and-play" environment of modern computers and consumer electronics, most acute care MEDICAL DEVICES are not designed to interoperate. MEDICAL DEVICES typically utilize proprietary protocols for system integration. These approaches do not provide the comprehensive integration capabilities necessary for safe, cross-MANUFACTURER MEDICAL DEVICE integration for data communication and MEDICAL DEVICE control for the care of a single high acuity PATIENT.

This standard series establishes the general principles for the design, verification, and validation of a model-based integration system that enables the creation of an INTEGRATED CLINICAL ENVIRONMENT intended to facilitate cross-MANUFACTURER MEDICAL DEVICE interoperability. This series of standards focuses especially on communication of PATIENT data and on equipment command and control, as well as on the functionality necessary for the seamless creation of an INTEGRATED CLINICAL ENVIRONMENT.

The approach defined and described by this series of standards for the INTEGRATED CLINICAL ENVIRONMENT (ICE) includes provisions for error resistance, and continual improvements in PATIENT safety, treatment efficacy and workflow efficiency based on device interoperability. [30]

Medical Devices and Medical Systems — Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) — Part 1: General requirements and conceptual model

1 * Scope

This standard specifies general requirements, a model and framework for integrating equipment to create a INTEGRATED CLINICAL ENVIRONMENT (ICE), as defined in 3.6. This standard specifies the characteristics necessary for the safe integration of MEDICAL DEVICES and other equipment, via an electronic interface, from different MANUFACTURERS into a single medical system for the care of a single high acuity PATIENT. This standard establishes requirements for a medical system that is intended to have greater error resistance and improved PATIENT safety, treatment efficacy and workflow efficiency than can be achieved with independently used MEDICAL DEVICES. [8]

This series of standards establishes requirements for design, verification, and validation processes of a model-based integration system for an INTEGRATED CLINICAL ENVIRONMENT.

This series of standards is intended to define the requirements essential for safety and thereby facilitate regulatory acceptance.

NOTE These requirements were derived to support the clinical scenarios or clinical concepts of operations described in Annex B.

2 Normative references

The following referenced documents are indispensable for the application of this document. The way in which these referenced documents are cited in normative requirements determines the extent (in whole or in part) to which they apply. For dated references, only the edition cited applies. However, parties to agreements based on this standard are encouraged to investigate the possibility of applying more recent editions of the normative documents indicated below. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 14971:2007, *Medical devices -- Application of risk management to medical devices*

IEC 60601-1-8:2006*, Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

IEC 62304:2006, *Medical device software – Software life cycle processes*

IEC 80001:——[1)] , *Application of risk management for IT-networks incorporating medical devices*

3 Terms and definitions

For the purposes of this document, the definitions given in ISO 14971:2007, IEC 60601-1-8:2006 and the following apply.

3.1
BASIC SAFETY
freedom from unacceptable RISK directly caused by physical hazards when a MEDICAL DEVICE is used under normal condition and single fault condition

[IEC 60601-1:2005, definition 3.10, modified]

3.2
CEC
CLINICAL ENVIRONMENT COORDINATOR
equipment, remote from the INTEGRATED CLINICAL ENVIRONMENT, that can control one or more INTEGRATED CLINICAL ENVIRONMENTS

EXAMPLE 1 Remote OPERATOR-interface for an ICE SUPERVISOR.

EXAMPLE 2 A 'central station' reviewing the information from multiple PATIENTS.

3.3
*** DEVICE MODEL**
representation of the capabilities of ICE-COMPATIBLE EQUIPMENT that includes the information needed to qualitatively and quantitatively describe, control and monitor its operation

NOTE 1 The MANUFACTURER chooses the capabilities that are exposed through the ICE EQUIPMENT INTERFACE.

NOTE 2 ASTM F-—— (Part 3) is intended to specify the requirements for a DEVICE MODEL.

3.4
ESSENTIAL PERFORMANCE
performance necessary to achieve freedom from unacceptable RISK

NOTE ESSENTIAL PERFORMANCE is most easily understood by considering whether its absence or degradation would result in an unacceptable RISK.

[IEC 60601-1:2005, definition 3.27]

3.5
FULLY COMPLIANT
type of ICE EQUIPMENT INTERFACE where the DEVICE MODEL is exported through the ICE EQUIPMENT INTERFACE to the ICE NETWORK CONTROLLER

1) To be published.

3.6
*** ICE**
INTEGRATED CLINICAL ENVIRONMENT
environment that combines interoperable heterogeneous MEDICAL DEVICES and other equipment integrated to create a medical system for the care of a single high acuity PATIENT

NOTE 1 An ICE can provide data acquisition, safety interlocks, system integration and distributed closed loop control.

NOTE 2 When supporting ICE functionality, the components that comprise an ICE typically function interdependently; they do not function independently.

NOTE 3 An ICE typically consists of an ICE SUPERVISOR, an ICE NETWORK CONTROLLER and one or more pieces of ICE-COMPATIBLE EQUIPMENT.

NOTE 4 Unlike a "Medical Electrical System" in IEC 60601-1:2005, ICE is presumed to comprise equipment from more than one MANUFACTURER. There is not necessarily a MANUFACTURER of the ICE, since combining equipment to form an ICE is the labeled intent of this equipment.

3.7
ICE-COMPATIBLE EQUIPMENT
MEDICAL DEVICE or other electrical equipment with an ICE EQUIPMENT INTERFACE

3.8
ICE EQUIPMENT INTERFACE
part of ICE-COMPATIBLE EQUIPMENT that provides the interface to the ICE NETWORK CONTROLLER

NOTE The ICE EQUIPMENT INTERFACE typically is an interface between software processes and is not an interface between the OPERATOR and ICE-COMPATIBLE EQUIPMENT.

3.9
ICE NETWORK CONTROLLER
part of an ICE that provides communication between ICE-COMPATIBLE EQUIPMENT and the rest of the ICE, using the DEVICE model

3.10
ICE SUPERVISOR
part of an ICE that provides a platform for functional integration between ICE-COMPATIBLE EQUIPMENT via the ICE NETWORK CONTROLLER and can provide application logic and an OPERATOR interface

NOTE 1 An ICE SUPERVISOR is equipment and software, not a person.

NOTE 2 Application logic can include clinical algorithms, distributed control integration and clinical decision support algorithms.

3.11
INTENDED USE
use for which a product, process or service is intended according to the specifications, instructions and information provided by the MANUFACTURER

[IEC 14971:2007, definition 2.5, modified]

3.12
MANUFACTURER
natural or legal person with responsibility for the design, manufacture, packaging, or labeling of a MEDICAL DEVICE, assembling a medical system, or adapting a MEDICAL DEVICE or a medical system, regardless of whether these operations are performed by that person or on that person's behalf by a third party

NOTE 1 ISO 13485 [30] defines “labeling” as written, printed or graphic matter
– affixed to a MEDICAL DEVICE or any of its containers or wrappers, or
– accompanying a MEDICAL DEVICE,
related to identification, technical description, and use of the MEDICAL DEVICE, but excluding shipping documents. In this standard, that material is described as markings and accompanying documents.

NOTE 2 “Adapting” includes making substantial modifications to a MEDICAL DEVICE or a medical system already in use.

NOTE 3 In some jurisdictions, the RESPONSIBLE ORGANIZATION can be considered a MANUFACTURER when involved in the activities described.

[IEC 60601-1:2005, definition 3.55, modified]

3.13
MEDICAL DEVICE
any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, 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 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 for medical purposes by means of *in vitro* examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which can be assisted in its function by such means

NOTE This definition has been developed by the Global Harmonization Task Force (GHTF). [31]

[ISO 14971:2007, definition 2.9]

EXAMPLE A MEDICAL DEVICE can be medical electrical equipment. [1]

3.14
MODEL COMPLIANT
type of ICE EQUIPMENT INTERFACE where the DEVICE MODEL is not exported through the ICE EQUIPMENT INTERFACE to the ICE NETWORK CONTROLLER, but is provided by other means

3.15
OPERATOR
person handling equipment

[IEC 60601-1:2005, definition 3.73]

3.16
PATIENT
living being (person or animal) undergoing a medical, surgical or dental procedure

[IEC 60601-1:2005, definition 3.76]

3.17
RESPONSIBLE ORGANIZATION
entity accountable for the use and maintenance of a MEDICAL DEVICE or a medical system

NOTE 1 The accountable entity can be, for example, a hospital, an individual clinician or a layperson. In home use applications, the PATIENT, OPERATOR AND RESPONSIBLE ORGANIZATION can be one and the same person.

NOTE 2 Education and training is included in "use."

[IEC 60601-1:2005, definition 3.101, modified]

4 *ICE conceptual functional model

4.1 Overview

A clinical benefit of integrating standalone MEDICAL DEVICES is the ability to combine the data collected from different sources to yield new information, in ways that are not possible with stand-alone MEDICAL DEVICES and equipment. Additional clinical benefits of integration by the ICE include decision support, the ability to implement distributed control of MEDICAL DEVICES for safety interlocks and closed loop control. Examples of such benefits are found in Annex B.

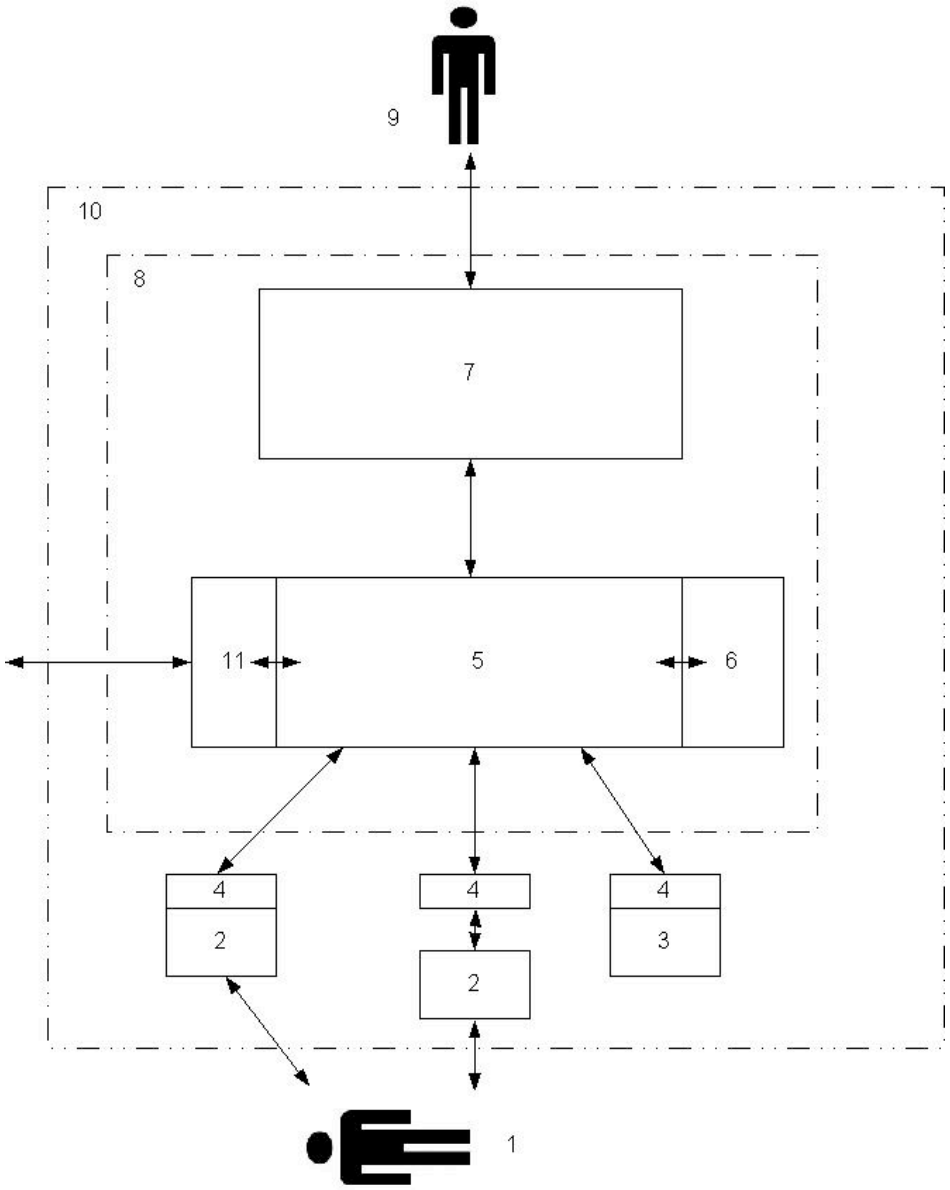
This standard introduces a specific conceptual functional model for defining the ICE. The model defines separate functions that comprise the ICE. In order to support essential safety this standard allocates requirements to defined functions of the ICE. This allows each MANUFACTURER to provide the functions of the ICE they have chosen to implement but not to provide the entire ICE.

The functional model includes an ICE NETWORK CONTROLLER, as defined in 3.9, one or more ICE EQUIPMENT INTERFACES, as defined in 3.8, and an ICE SUPERVISOR, as defined in 3.10, which allows the RESPONSIBLE ORGANIZATION to manage the RISK of integrating a collection of Information and Communication Technologies (ICT) equipped MEDICAL DEVICES into an ICE, the subject of this Standard.

NOTE ICT includes common computers, printers and networking interfaces and equipment.

The model is a functional representation of the ICE and not a representation of the physical configuration. Different deployments and physical connections of the functions depicted may be used and equipment containing the functions need not be co-located.

Figure 1 depicts the conceptual functional model, which serves as the foundation of this series of standards.



Key

1	PATIENT	7	ICE SUPERVISOR
2	MEDICAL DEVICE	8	ICE manager
3	equipment	9	OPERATOR
4	ICE EQUIPMENT INTERFACE	10	ICE
5	ICE NETWORK CONTROLLER	11	external interface
6	data logger		

NOTE 1 Figure 1 is not intended to represent a specific physical configuration of ICE components, but to represent the functional relationships between the major elements of an ICE.

NOTE 2 A MEDICAL DEVICE or equipment can or need not have OPERATOR-accessible interfaces.

Figure 1 — Conceptual functional model showing the elements of the INTEGRATED CLINICAL ENVIRONMENT

ICE deployments may include the following physical configurations:

a) ICE NETWORK CONTROLLER and ICE SUPERVISOR incorporated together and deployed as a standalone ICE manager (Figure 1, items 5 and 7 combined together as item 8);

b) ICE NETWORK CONTROLLER and ICE SUPERVISOR deployed independently (Figure 1, items 5 and 7 as separate equipment);

c) A single MEDICAL device with an incorporated ICE manager (Figure 1, items 2 and 8 combined together);

EXAMPLE 1 A ventilator that includes an ICE manager.

d) A single MEDICAL DEVICE with an incorporated ICE EQUIPMENT INTERFACE (Figure 1, items 2 and 4 combined together); and

EXAMPLE 2 A pulse oximeter that includes an ICE EQUIPMENT INTERFACE.

e) An external ICE EQUIPMENT INTERFACE that interconnects a MEDICAL DEVICE with the ICE NETWORK CONTROLLER INTERFACE (Figure 1, items 2 and 4 as separate equipment).

EXAMPLE 3 An external ICE EQUIPMENT INTERFACE that connects a sphygmomanometer to an ICE NETWORK CONTROLLER.

4.2 ICE NETWORK CONTROLLER

4.2.1 * General

The ICE NETWORK CONTROLLER is responsible for:

a) ensuring that the functional capabilities, in accordance with the non-functional requirements in the DEVICE MODEL of the ICE-COMPATIBLE EQUIPMENT, can be reliably delivered to the ICE SUPERVISOR; or

b) generating a TECHNICAL ALARM CONDITION that indicates that the required performance cannot be delivered.

EXAMPLE A TECHNICAL ALARM CONDITION generated when the ICE NETWORK CONTROLLER has insufficient available resources (e.g. bandwidth) to support newly installed ICE-COMPATIBLE EQUIPMENT.

The ICE NETWORK CONTROLLER shall provide association and communication with each attached ICE EQUIPMENT INTERFACE by interpreting the DEVICE MODEL.

NOTE 1 ASTM F-—— (Part 2) is intended to specify the requirements for an ICE NETWORK CONTROLLER including such items as compatibility checks, arbitration of the different communication paths, error detection, error logging, protocol adaptation, semantic normalization and ICE-COMPATIBLE EQUIPMENT identification, authentication and authorization.

NOTE 2 ASTM F-—— (Part 3) is intended to specify the requirements for a DEVICE MODEL.

4.2.2 ICE NETWORK CONTROLLER interface

A port on the ICE NETWORK CONTROLLER provides communication to an ICE EQUIPMENT INTERFACE, covering layers 1 to 4 of the ISO OSI reference model. [1] A key objective is to make the implementation of the upper layers of the communication stack of the ICE NETWORK CONTROLLER independent of the particular ICE EQUIPMENT INTERFACE.

An ICE NETWORK CONTROLLER shall provide:

a) Communication ports to connect to ICE EQUIPMENT INTERFACES.

EXAMPLE 1 an Ethernet port

EXAMPLE 2 an ISO 11073 (series), point-of-care MEDICAL DEVICE communication port

EXAMPLE 3 a universal serial bus (USB) port

EXAMPLE 4 an RS-232 port

EXAMPLE 5 a controller area network (CAN) port

EXAMPLE 6 an IEEE 802.11 port

EXAMPLE 7 an IEEE 802.15.1 (Bluetooth) port

EXAMPLE 8 an IEEE 802.15.4 (ZigBee) port

b) An interface to support connection to an ICE SUPERVISOR**.** An ICE NETWORK CONTROLLER and an ICE SUPERVISOR may be integrated together.

NOTE Such an integrated ICE NETWORK CONTROLLER and ICE SUPERVISOR is referred to as an 'ICE manager'.

Check compliance by inspection.

4.2.3 * External interface

An ICE NETWORK CONTROLLER shall be equipped with a separate interface to communicate externally from the ICE. More than one external interface may be provided. This interface may be used for one or more of the following:

a) Connection to the professional healthcare facility network backbone;

b) Connection to the public switched network;

c) Connection to the internet;

EXAMPLE External interface utilizing the Integrating the Healthcare Enterprise (IHE) Patient Care Devices (PCD) technical framework. [32]

d) Connection to a CLINICAL ENVIRONMENT COORDINATOR;

e) Connection via a CLINICAL ENVIRONMENT COORDINATOR by delegation or proxy.

NOTE A CLINICAL ENVIRONMENT COORDINATOR supports multiple INTEGRATED CLINICAL ENVIRONMENTS.

The MANUFACTURER of an ICE NETWORK CONTROLLER shall develop a qualification test suitable for use by a RESPONSIBLE ORGANIZATION to verify operation of the external interface. This qualification test shall be disclosed in the technical description.

The technical description shall include a reference to IEC 80001:—[2] and the necessity of the RESPONSIBLE ORGANIZATION to perform RISK MANAGEMENT, including the qualification test for the equipment, prior to placing the system into service.

The instructions for use shall include an indication that this qualification test is described in the technical description and is required to be performed prior to placing the equipment into service.

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2 To be published.

Check compliance by inspection of the instructions for use and the technical description.

4.2.4 * Forensic data logging

The ICE NETWORK CONTROLLER shall be equipped with a means to provide data logging, stamped with a common time base, of the accessible "state-of-the-clinical environment". This means may be external to the ICE NETWORK CONTROLLER.

NOTE ASTM F-—— (Part 2) is intended to specify the requirements for an ICE NETWORK CONTROLLER including the forensic data logging of the "state-of-the-clinical environment".

4.3 *ICE SUPERVISOR

The ICE SUPERVISOR is responsible for:

a) ensuring that the functional capabilities and the non-functional requirements, as indicated by the ICE NETWORK CONTROLLER, are suitable for the INTENDED USE of the ICE SUPERVISOR; or

b) generating a TECHNICAL ALARM CONDITION that indicates that the required capabilities cannot be delivered.

EXAMPLE A TECHNICAL ALARM CONDITION is generated when the newly installed ICE-COMPATIBLE EQUIPMENT has insufficient capability (e.g. pulse oximeter averaging time is too long) to permit the ICE SUPERVISOR (e.g. a transient hypoxia monitoring algorithm) to achieve its INTENDED USE.

NOTE ASTM F-—— (Part 4) is intended to specify the requirements for an ICE SUPERVISOR.

4.4 * ICE EQUIPMENT INTERFACE

The ICE EQUIPMENT INTERFACE shall be either FULLY COMPLIANT or MODEL COMPLIANT.

EXAMPLE 1 A DEVICE MODEL provided for a MODEL COMPLIANT legacy device is captured in a file that is manually installed on the ICE NETWORK CONTROLLER.

EXAMPLE 2 A DEVICE MODEL provided for a FULLY COMPLIANT device uploads automatically through the ICE EQUIPMENT INTERFACE to the ICE NETWORK CONTROLLER.

NOTE ASTM F-—— (Part 3) is intended to specify the requirements for a DEVICE MODEL.

5 General requirements

5.1 RISK MANAGEMENT PROCESS

A RISK MANAGEMENT PROCESS complying with ISO 14971:2007 shall be performed for an ICE SUPERVISOR, an ICE NETWORK CONTROLLER and an ICE EQUIPMENT INTERFACE.

In applying ISO 14971:2007:

— The term 'medical device' shall assume the same meaning as a MEDICAL DEVICE incorporating an ICE EQUIPMENT INTERFACE.

— The policy for determining acceptable RISK and the acceptability of RESIDUAL RISK(S) shall be established by the MANUFACTURER.

Check compliance by inspection of the RISK MANAGEMENT FILE. The requirements of this subclause are considered to be satisfied if the MANUFACTURER has:

— *established a RISK MANAGEMENT PROCESS;*

— *established acceptable levels of RISK; and*

— *demonstrated that the RESIDUAL RISK(S) is acceptable (in accordance with the policy for determining acceptable RISK).*

5.2 * ICE EQUIPMENT INTERFACE qualification test

The MANUFACTURER of equipment that includes an ICE EQUIPMENT INTERFACE shall develop a qualification test suitable for use by a RESPONSIBLE ORGANIZATION to verify those portions of the BASIC SAFETY and ESSENTIAL PERFORMANCE of that ICE-COMPATIBLE EQUIPMENT that can be affected by the ICE EQUIPMENT INTERFACE. This qualification test shall be disclosed in the technical description.

The technical description shall include a reference to IEC 80001:—[3)] and the necessity of the RESPONSIBLE ORGANIZATION to perform RISK MANAGEMENT, including the qualification test for the ICE-COMPATIBLE EQUIPMENT, prior to placing the system into service.

The instructions for use shall include an indication that this qualification test is described in the technical description and is required to be performed prior to placing the equipment into service.

Check compliance by inspection of the instructions for use and technical description.

5.3 Software

The requirements of IEC 62304:2006 shall apply to the software of an ICE NETWORK SUPERVISOR, an ICE NETWORK CONTROLLER and an ICE EQUIPMENT INTERFACE.

Check compliance by inspection of the validation reports demonstrating compliance with the requirements of IEC 62304:2006.

5.4 Communication management

The ICE shall maintain BASIC SAFETY and ESSENTIAL PERFORMANCE in NORMAL CONDITION and SINGLE FAULT CONDITION. The following principles are intended to guide the development of the other parts of this standard:

a) The connected ICE-COMPATIBLE EQUIPMENT does not fail due to receipt of messages or other information; and

b) The ICE NETWORK CONTROLLER does not fail due to receipt of messages or other information that do not conform to the DEVICE MODEL of the sending connected ICE-COMPATIBLE EQUIPMENT;

Specific error scenarios to be considered in the verification of ICE-COMPATIBLE EQUIPMENT should include the following:

c) failures caused by direct or indirect connection, electrical and logical, of ICE components to the ICE-COMPATIBLE EQUIPMENT;

3) To be published.

d) failures caused by erroneous commands;

e) failures caused by receiving and processing erroneous data or commands; and

f) failures caused by not adhering to the non-functional requirements of the communication specification.

Check compliance by application of the tests of the remaining parts of ASTM F2761.

5.5 ALARM SYSTEM

The requirements of IEC 60601-1-8:2006 shall apply to the equipment in the ICE.

In applying IEC 60601-1-8:2006:

— the term 'medical electrical equipment' or 'me equipment' shall assume the same meaning as MEDICAL DEVICES or other electrical equipment with an ICE EQUIPMENT INTERFACE;

— the term 'medical electrical system' or 'me system' shall assume the same meaning as the ICE.

Check compliance by application of the tests of IEC 60601-1-8:2006.

Annex A
(informative)

Guidance and rationale

A.1 General guidance

This Annex provides a rationale and guidance for certain requirements of this standard and is intended for those who are familiar with the design and use of the INTEGRATED CLINICAL ENVIRONMENT but who have not participated in its development. An understanding of the reasons for these requirements is provided to aid in the application of this standard. Furthermore, as clinical practice and technology change, it is believed that a rationale for the present requirements will facilitate a revision of this standard necessitated by those developments.

A.2 Rationale and guidance for particular clauses and subclauses

The numbering of the following rationale corresponds to the numbering of the clauses and subclauses in this document.

Clause 1 Scope

One of the primary incentives for developing this series of standards was to support the integration of MEDICAL DEVICES across a variety of clinical contexts in an efficient manner. MEDICAL DEVICES are essential for the practice of modern medicine. However, unlike the inter-connected "plug-and-play" environment of modern computers and consumer electronics, most acute care MEDICAL DEVICES are not designed to interoperate. The importance of applying modern systems engineering solutions, such as interoperability, to improve PATIENT SAFETY and reduce costs was addressed in a National Academy of Sciences report. [18] Typically when such MEDICAL DEVICE integration is required, customized MEDICAL DEVICE interfaces need to be developed, which, in addition to increasing costs and development time, might not provide the required functionality. The objective of this series of standards is to enable the implementation of such an integrated (interoperable) medical system by describing the requirements for the INTEGRATED CLINICAL ENVIRONMENT. These requirements are intended to address the clinical, technical, regulatory, and legal concerns for an ICE while providing acceptable RESIDUAL RISK, (i.e. RISK remaining after RISK CONTROL measures have been taken).

Some standards exist that are intended to achieve interoperability between independent medical systems. Further standards are needed for networking MEDICAL DEVICES in order to enable safe cross-MANUFACTURER MEDICAL DEVICE interoperability that creates an INTEGRATED CLINICAL ENVIRONMENT composed of interdependent MEDICAL DEVICES and other equipment. Each MEDICAL DEVICE is required to interface with the ICE NETWORK CONTROLLER in order to provide a description of the available MEDICAL DEVICE data, functionality, sensor and actuator capabilities and behavior. The DEVICE MODEL includes these attributes. To support integration of such MEDICAL DEVICES into an ICE, this series of standards includes capabilities to permit an ICE SUPERVISOR to monitor and control the MEDICAL DEVICES via the network. Figure 1 shows a conceptual model describing the relationships between the functional elements of the INTEGRATED CLINICAL ENVIRONMENT, i.e., the ICE, consisting of an ICE SUPERVISOR, an ICE NETWORK CONTROLLER and an ICE-COMPATIBLE EQUIPMENT, as well as the OPERATOR and PATIENT.

The integration of individual MEDICAL DEVICES into a PATIENT-centric ICE can provide real-time comprehensive data for the healthcare information system/electronic medical record/electronic health record (HIS/EMR/EHR), and can support advances in PATIENT safety [7],[11],[33],[34],[35],[36] and workflow improvements such as:

- Clinical decision support;
- Automated workflow support;
- MEDICAL DEVICE safety interlocks;
- Reduction of use errors; [7]
- Distributed physiologic closed-loop control [6] of e.g., medication, fluid delivery, anesthetic agent delivery, and ventilation;
- Monitoring of MEDICAL DEVICE activity and performance;
- Automated system readiness assessment (e.g., prior to starting invasive clinical procedures);
- Support of remote monitoring of the intensive care unit;
- Safeguarding of protected PATIENT information through real-time encryption;
- Seamless connection and disconnection ("plug-and-play") of MEDICAL DEVICES [38] without shutting down and re-booting the MEDICAL DEVICES or the ICE NETWORK CONTROLLER ("hot swapping");
- Facilitation of disaster preparedness: real-time inventory of equipment in use and in strategic national stockpiles, and rapid deployment of MEDICAL DEVICES in makeshift emergency-care settings;
- Avoidance of unnecessary redundancy by using shared resources, e.g. one connection to the electronic medical record (EMR);
- Reduction of the cost and implementation barriers to technology-dependent innovation.

Definition 3.3 DEVICE MODEL

The DEVICE MODEL is used to communicate the specific capabilities and behavior of a particular piece of ICE-COMPATIBLE EQUIPMENT. The DEVICE MODEL needs to be specific enough that it permits the ICE CONTROLLER to receive and understand data from the ICE-COMPATIBLE EQUIPMENT as well as to send data to and control the ICE-COMPATIBLE EQUIPMENT. Furthermore, the DEVICE MODEL is used by the ICE SUPERVISOR to determine whether the connected ICE-COMPATIBLE EQUIPMENT is suitable for its intended use. To accomplish this, the DEVICE MODEL includes descriptions of inputs, outputs, operational modes, and mathematical models of ICE-COMPATIBLE EQUIPMENT behavior. The mathematical model of ICE-COMPATIBLE EQUIPMENT behavior, by allowing a determination of compatibility, permits the interchange of different ICE-COMPATIBLE EQUIPMENT while maintaining the desired clinical functionality, safety and efficacy.

The DEVICE MODEL represents the characteristics of the data flowing in and out of the MEDICAL DEVICE through the DEVICE MODEL. It describes, in machine and human readable format, the concept that a data parameter represents (e.g., blood pressure, O_2 concentration, pulse rate), the units of representation (e.g., mmHg, beats/min), and the bit encoding of the parameter (e.g., 16-bit fixed point, 32-bit floating point). Data parameters can represent physiological measurements of the PATIENT, time of measurement, state of the MEDICAL DEVICE, etc. The DEVICE MODEL also includes a state space representation of the MEDICAL DEVICE. The ICE EQUIPMENT INTERFACE of ICE-COMPATIBLE EQUIPMENT can be either FULLY COMPLIANT or MODEL COMPLIANT, i.e., the DEVICE MODEL is communicated through the ICE EQUIPMENT INTERFACE or is provided by other means. The MANUFACTURER chooses the capabilities that are exposed through the ICE EQUIPMENT INTERFACE.

An important requirement of the ICE is maintenance of adequate resources to ensure that the non-functional requirements of communication are met. These non-functional requirements are sometimes referred to as communication Quality of Service (QoS) and can include bandwidth, latency, and jitter. These non-functional

requirements need to be characterized and included in the DEVICE MODEL to ensure safe and effective operation. Under circumstances where the non-functional requirements of the end application cannot be met, the ICE SUPERVISOR or other appropriate ICE components need to respond accordingly, e.g. by generating a TECHNICAL ALARM CONDITION.

Many existing MEDICAL DEVICES use one of the standard transport pipes and standard semantics described in this Annex. What they cannot do is automatically associate with an ICE NETWORK CONTROLLER and export their DEVICE MODEL to it. Such MEDICAL DEVICES are not FULLY COMPLIANT. However, if the DEVICE MODEL of the MEDICAL DEVICE includes a description of its native application layer protocol, and that DEVICE MODEL can be made available to the ICE NETWORK CONTROLLER ahead of time, the two can interact. While this is not strictly plug-and-play (it is more like prime, plug and play) it allows an ICE NETWORK CONTROLLER to interact with legacy equipment in a clinical environment—without modifications to itself unique to a particular MEDICAL DEVICE. Such MEDICAL DEVICES are MODEL COMPLIANT.

Thus, ICE-COMPATIBLE EQUIPMENT needs to be at least MODEL COMPLIANT with this standard before integration via the standard (as opposed to point solutions) can be realized. An overly constrained specification results in MEDICAL DEVICES that can interoperate only with others built to the same specification, and thus can impede its own adoption due to the low return-on-investment to early adopters. An insufficiently constrained specification can cause the production of MEDICAL DEVICES that can fail to interoperate properly in unexpected ways.

The model-based approach prescribed in this standard differentiates between those aspects of a MEDICAL DEVICE that are required to be constrained to a unique implementation and those that need not be so constrained. In particular, the meta-model framework for specifying the DEVICE MODEL of the MEDICAL DEVICE needs to be commonly understood, so that an ICE NETWORK CONTROLLER can interpret it. Nevertheless, the data communications mechanism and the semantics employed by each MEDICAL DEVICE need not be unique, as long as they are drawn from a prescribed set of extant industry standards. While a given MEDICAL DEVICE implicitly has a single protocol on a digital interface it provides to a higher-level device (i.e., it employs one syntax and semantics), there is no reason to constrain an ICE NETWORK CONTROLLER to be so. It is reasonable and beneficial to allow a “multi-communication protocol” ICE NETWORK CONTROLLER.

Definition 3.6 INTEGRATED CLINICAL ENVIRONMENT (ICE)

An INTEGRATED CLINICAL ENVIRONMENT is an environment where monitoring, treatment or diagnosis is performed on a single PATIENT, with interconnected MEDICAL DEVICES and other equipment. The environment contains the ICE SUPERVISOR, ICE NETWORK CONTROLLER, connected ICE-COMPATIBLE EQUIPMENT supporting the PATIENT or the procedure, and can interface with external databases. While many of the elements of a clinical environment exist in a bounded physical space containing the PATIENT (e.g., an operating room, intensive care unit, field hospital, ambulance, or other acute care environments), they need not all be within that physical space. Some of the OPERATORS, some pieces of equipment (e.g., control consoles), or databases can be located at remote locations.

An INTEGRATED CLINICAL ENVIRONMENT is PATIENT-centric. As a PATIENT moves among different venues (e.g., operating room, ICU, emergency department, transport, home) the ICE moves with the PATIENT; however some of the elements of the ICE (OPERATORS, MEDICAL DEVICES, and even the ICE NETWORK CONTROLLER or ICE SUPERVISOR) can change.

NOTE The PATIENT can be the OPERATOR.

In IEC 60601-1:2005, an 'me system' is presumed to have one MANUFACTURER that can be the RESPONSIBLE ORGANIZATION. An ICE is presumed to comprise equipment from more than one MANUFACTURER where the labeled intent of this equipment is to interoperate with ICE-COMPATIBLE EQUIPMENT. As a result, there is not necessarily a MANUFACTURER of the ICE, since combining equipment to form an ICE is the labeled intent of this equipment.

Subclause 4.2 ICE NETWORK CONTROLLER

The ICE NETWORK CONTROLLER needs to know the semantics employed in the DEVICE MODEL in order to name the parameters of that MEDICAL DEVICE and its various aspects, such as units of measure. There are about two dozen standardized semantics in use related to various aspects of medicine (e.g., HL-7[4] , DICOM[5]). They are both complementary and overlapping. Devices address a particular clinical domain. The semantics of one domain might not apply to another (e.g., the units of data representation in one domain might not exist in the other). A future part of this series of standards could define common semantics for naming characteristics in the DEVICE MODEL, but this is unnecessary because the name/concept relations already exist in extant standards. It is only necessary that it identify in a DEVICE MODEL which semantics is being used. If necessary, the DEVICE MODEL could reference different semantics standards in different parts of itself, as appropriate.

The ICE NETWORK CONTROLLER needs to know the application layer protocol used by each MEDICAL DEVICE. The DEVICE MODEL defines this protocol. The DEVICE MODEL is used to set up and maintain a logical association between a MEDICAL DEVICE and the ICE NETWORK CONTROLLER, and to transfer commands and data between the MEDICAL DEVICE and the ICE NETWORK CONTROLLER. An association protocol allows the ICE NETWORK CONTROLLER to “discover” any MEDICAL DEVICES that are connected to it. As part of the association PROCESS, the MEDICAL DEVICE exports or identifies its DEVICE MODEL to the ICE NETWORK CONTROLLER. This association capability is what produces the system characteristic informally described as “plug-and-play” — plug a device into a network and the two establish a relationship automatically. To achieve this, the MEDICAL DEVICE is required to implement some part of the association protocol that the ICE NETWORK CONTROLLER can understand, without any previous ICE NETWORK CONTROLLER knowledge of the MEDICAL DEVICE.

The aspects of communication protocols of concern in communicating between MEDICAL DEVICES are:

a) The physical medium of information transfer, including connectors for wired communications channels (layer 1 of the Open Systems Interconnection or OSI communication model);

b) The protocols used for data transport on that medium (layers 2-4 of the Open Systems Interconnection or OSI model)—the communications stack;

c) The semantics of the data exchanged between the ICE NETWORK CONTROLLER and a MEDICAL DEVICE;

d) The application level protocols between the ICE NETWORK CONTROLLER and a MEDICAL DEVICE.

Usually the communication medium and stack are bundled to produce a data transport pipe, e.g., TCP/IP[6] over Ethernet. While there are various flavors of Ethernet, the higher speed versions are generally compatible with the lower speed versions. Backwards compatibility is usually retained as these transport pipes evolve their operating speeds. There are a small number of practical choices for a MEDICAL DEVICE that have been, or are likely to be used in the future, including TCP/IP over Ethernet (including Powerlink Ethernet), USB, RS-232, 802.11 wireless variations, and CAN. To implement one of these pipes, an ICE NETWORK CONTROLLER needs a hardware interface and drivers (the stack protocol handlers) for that interface. One can envision an ICE NETWORK CONTROLLER as a PC/Workstation with slots to plug in the appropriate interfaces. Older ICE NETWORK CONTROLLER implementations could be updated with the addition of an I/O card and the stack drivers that come with it.

The critical element enabling the interaction between the ICE NETWORK CONTROLLER and a wide variety of MEDICAL DEVICES is the meta-model framework used to characterize MEDICAL DEVICE functionality and application layer interactions. The meta-model framework is the main objective of ASTM F-——— (Part 3). For an

4) See http://www.hl7.org

5) See http://medical.nema.org

6) Transport control protocol/internet protocol

ICE NETWORK SUPERVISOR to react intelligently to the information obtained from the array of MEDICAL DEVICES through the ICE NETWORK CONTROLLER in the clinical environment, it has to employ other models—of PATIENT physiology and OPERATOR activities. Specifying the frameworks needed to represent all of these models, as well as the framework for representing the rules relating the data in the clinical environment, is the main objective of ASTM F—— (Part 3).

Subclause 4.2.1 General

The ICE NETWORK CONTROLLER supports the following PATIENT-centric capabilities of the INTEGRATED CLINICAL ENVIRONMENT:

— Provide an external interface;

EXAMPLE 1 Provide relevant MEDICAL DEVICE data to a clinical information system.

EXAMPLE 2 Provide relevant clinical data to a healthcare information system/electronic medical record/electronic health record (HIS/EMR/EHR).

EXAMPLE 3 Retrieve relevant PATIENT information from HIS/EMR/EHR.

EXAMPLE 4 Provide relevant information to support a healthcare equipment management system.

— Provide data logs for forensic analysis (similar to a flight data recorder);

— Provide seamless connection and disconnection ("plug-and-play") of MEDICAL DEVICES and other devices without shutting down and re-booting the MEDICAL DEVICES or the ICE NETWORK CONTROLLER ("hot swapping");

— Perform network control functions independently of the underlying data communication mechanization (layers 1-4 of ISO/IEC 7498-1);

— Provide a common time base and binding of data to PATIENT identity;

— Interface with equipment that contains an ICE EQUIPMENT INTERFACE;

— Interface with an ICE SUPERVISOR.

Subclause 4.2.3 External interface

This interface is necessary for populating the electronic medical record, equipment inventory, admit/discharge/transfer information, and billing information. This interface could also be used for electronic updating of the ICE NETWORK CONTROLLER or the attached ICE SUPERVISOR or equipment. The MANUFACTURER should take into consideration the privacy and security of PATIENT information. It is expected that the external interface will be the subject of a future part of this series of standards.

An external interface can also provide connection to one or more CLINICAL ENVIRONMENT COORDINATORS (CECs). A CEC can remotely access the capabilities of the ICE SUPERVISOR.

Uses of a CEC can include:

a) secondary or remote OPERATOR-interface for an ICE SUPERVISOR;

b) a paging system acting as a DISTRIBUTED ALARM SYSTEM for more than one ICE; and

c) a gateway acting as a proxy for external interface connectivity.

Subclause 4.2.4 Forensic data logging

The purpose of the forensic data logging is to provide information that can be used to distinguish between, for example, use error, abnormal use, ICE-COMPATIBLE EQUIPMENT failure, ICE SUPERVISOR failure, or ICE NETWORK CONTROLLER failure. [7] Forensic data logging is expected to be used to analyze incidents and near incidents, analogously to an airplane's flight data recorder.

This requirement is intended to support forensic analysis of the ICE. The sources of the stored data need to include, at a minimum, technical status data (the technical "state-of-the-clinical-environment") available from all interconnected components of the ICE (see Figure 1).

The forensic data logging is intended to facilitate system integration, system deployment, and retrospective analysis of performance, incidents and near incidents. To accomplish these tasks the forensic data logging should collect:

a) ICE-COMPATIBLE EQUIPMENT technical variables and TECHNICAL ALARM CONDITIONS available to the ICE NETWORK CONTROLLER;

b) PATIENT physiological variables and PHYSIOLOGICAL ALARM CONDITIONS from ICE-COMPATIBLE EQUIPMENT available to the ICE NETWORK CONTROLLER;

c) ICE NETWORK CONTROLLER commands to ICE-COMPATIBLE EQUIPMENT;

d) ICE NETWORK CONTROLLER status;

e) Any other significant events and errors.

EXAMPLE Storage of any ALARM SIGNAL inactivation state.

Additionally, the data logging should, among other things, include:

f) OPERATOR commands to the ICE NETWORK CONTROLLER;

g) ICE SUPERVISOR status;

h) OPERATOR commands to the ICE SUPERVISOR;

i) Anomalies in ICE determined by the ICE SUPERVISOR;

j) The state of workflow plan execution and deviations from nominal of all variables per the workflow plan;

k) External data consumed and external commands and controls.

The ICE NETWORK CONTROLLER should log all OPERATOR inputs to ICE-COMPATIBLE EQUIPMENT.

Consideration should be given to protecting the integrity and security of the forensic data log. Consideration should be given to restricting access to the data log to the RESPONSIBLE ORGANIZATION.

Subclause 4.3 ICE SUPERVISOR

The ICE SUPERVISOR is intended to support the following PATIENT-centric capabilities of the INTEGRATED CLINICAL ENVIRONMENT:

— Provide safety interlocks;

— Distribute integrated ALARM CONDITIONS to relevant OPERATORS;

— Provide context-aware clinical decision support;

— Set command input variables of other MEDICAL DEVICES, per OPERATOR-defined, context-appropriate rules, in order to manage their operation;

— Assess the readiness of MEDICAL DEVICES to support specified functions or clinical workflow;

— Combine ALARM CONDITIONS from multiple MEDICAL DEVICES for integrated OPERATOR display, notification and reporting;

— Utilize the data available from, and control the operation of, each MEDICAL DEVICE (as characterized by the DEVICE MODEL provided by each MEDICAL DEVICE) in the clinical environment to the extent permitted by each MEDICAL DEVICE;

— Perform automated record keeping;

— Support remote access and control of MEDICAL DEVICES.

Subclause 4.4 ICE EQUIPMENT INTERFACE

The ICE EQUIPMENT INTERFACE is intended to facilitate interoperability between the ICE NETWORK CONTROLLER and ICE-COMPATIBLE EQUIPMENT. Key requirements for such interoperability include:

a) Common interconnection hardware between the ICE Network Controller the Medical Device (the “ICE equipment interface port”) with services providing data exchange capabilities;

b) A common set of communication protocols, typically consisting of an information model, a service model and a set of protocol data structures mapping the models to messages that are exchanged between the ICE NETWORK CONTROLLER and the ICE-COMPATIBLE EQUIPMENT; and

c) A set of semantics (a terminology) to uniquely identify concepts of represented data, such as measurements and controls.

These requirements can be easily mapped to the OSI Basic Reference Model (OSI/RM) [see ISO 7498-1]. The lower layers (Physical, Data Link, Network, and Transport Layers) provide a transport interface that defines the interconnection hardware and basic properties of the data exchange. The upper layers (Session, Presentation, and Application Layers) provide the communication models, data message definitions and the set of semantics.

It is the purpose of the DEVICE MODEL to precisely define all the communication layers, along with Quality of Service aspects and specific device capabilities. This enables a mapping of the capabilities of the MEDICAL DEVICE, as represented via the communication port, to the functions of the ICE NETWORK CONTROLLER.

The complexity of such a mapping can be significantly reduced, or even eliminated, by the use of standard communication protocols for medical device communication. Relevant standards and standardization activities in this field include:

- ISO 8802/IEEE 802 series[2]

IEEE 802 refers to a family of IEEE standards dealing with local area networks and metropolitan area networks. The services and protocols specified in IEEE 802 map to the lower two layers (Data Link and Physical) of the seven-layer OSI networking reference model.

- ISO/IEEE P11073 series for Standard for Medical Device Communications[3]

712 This series of standards defines methods for providing interconnection and interoperability of medical devices.

713 - IHE PCD Profile[14]

714 IHE (Integrating the Healthcare Enterprise) is an initiative by healthcare professionals and industry to improve
715 the way computer systems in healthcare share information. The Patient Care Device (PCD) Domain is
716 concerned with use cases in which at least one actor is a regulated PATIENT-centric point-of-care MEDICAL DEVICE
717 that communicates with at least one other actor such as a MEDICAL DEVICE or information system.

718 The sub-parts of the ICE standard (ASTM F-—— (Part 2) and ASTM F-—— (Part 3)) leverage these standards
719 and initiatives to enable reuse of existing definitions where possible, and avoid potentially conflicting standards
720 in the field of MEDICAL DEVICE communication. At the same time, the use models presented in this document are
721 directly applicable to the above mentioned standards and initiatives and are therefore expected to be
722 appropriately considered in the ongoing development work in these groups.

Annex B
(informative)

Clinical context and clinical scenarios

B.1 Purpose and introduction

B.1.1 Purpose

The purpose of this Annex is to provide the clinical context for the development of standards for integrated medical device systems. The Clinical Scenarios below illustrate serious adverse events that could have been prevented through integrated medical systems, thus representing unmet safety and performance needs. The examples are representative, not exhaustive.

The Medical Device "Plug-and-Play" Interoperability program [19][37] has identified high-level Clinical Scenarios from clinical publications, web sites, and interviews ("focus groups") with clinicians and engineers. [20],[21] These scenarios have been expanded into "use cases" to aid in the development of appropriate integrated medical device system standards.[24]

B.1.2 Methodology

For participants in the focus groups, a context statement and sample questions were used to stimulate their thinking.

Typical instructions and background for participants:

> *Assume that the integrated medical system provides seamless connectivity of medical devices to allow communication (e.g. remote data display, population of the electronic medical record, etc.) and integration of medical devices with control functions (e.g. control of infusion pumps from the anesthesia workstation, implementation of "safety interlocks" to stop an infusion at a pre-determined blood pressure value or to prevent intra-abdominal CO_2 insufflation if the heart rate and blood pressure are unmonitored, etc.).*
>
> *Assume that there are no technical, economic, legal or regulatory obstacles to deploying a comprehensive system. Define the high-level clinical needs without specifying the details of the technical specifications.*
>
> *a) Which clinical challenges exist today that could be solved by the proposed system?*
>
> *b) Which obstacles to safety, efficiency, and teamwork could be reduced or eliminated by the proposed system?*
>
> *c) How would this approach affect the practice environment, both clinically and from a business/process perspective?*
>
> *d) What risks can be introduced by an integrated medical system, and how could they be mitigated?*

In the representative clinical use cases below, the Clinical Scenario is described first, followed by the Clinical Concept of Operations, as defined herein:

B.1.3 Clinical scenario

A Clinical Scenario is a brief description of a clinical situation or event. The purpose of the Clinical Scenarios in this document is to provide background and illustrate the need for the development of technical solutions. Two Clinical Scenarios are provided for each situation:

a) the Current State typically describes an adverse event that has occurred to a patient;

b) the Proposed State is a brief illustration of the improvement in safety and effectiveness obtained by applying an integrated solution.

B.1.4 Clinical concept of operations (CConOps)

A Clinical Concept of Operations (CConOps) is a more detailed description of how devices and clinical staff could interoperate in a clinical environment.

This description provides details of:

— The type of equipment utilized;

— The clinical processes required;

— The type or category of clinical staff;

EXAMPLES Surgeon, intensivist, anesthesia provider, chief nurse, nursing assistant, respiratory therapist.

— Potential changes or new/novel equipment or workflow that does not exist today but that could improve the process (optional);

— Benefits of the proposed process; and

— Risk analysis of the proposed process.

Each CConOps detailed below permits an improvement in safety and effectiveness via a specific solution implementing the Proposed State.

B.2 Clinical Examples

B.2.1 Safety Interlocks

B.2.1.1 Clinical scenario, safety Interlock

Current State: “A 49-year-old woman underwent an uneventful total abdominal hysterectomy and bilateral salpingo-oophorectomy. Postoperatively, the patient complained of severe pain and received intravenous morphine sulfate in small increments. She began receiving a continuous infusion of morphine via a patient-controlled analgesia (PCA) pump. A few hours after leaving the PACU [post anesthesia care unit] and arriving on the floor [hospital ward], she was found pale with shallow breathing, a faint pulse, and pinpoint pupils. The nursing staff called a “code,” and the patient was resuscitated and transferred to the intensive care unit on a respirator [ventilator]. Based on family wishes, life support was withdrawn and the patient died. Review of the

case by providers implicated a PCA overdose." [10] Delayed detection of respiratory compromise in PATIENTS undergoing PCA therapy is not uncommon because monitoring of respiratory status has been confounded by excessive nuisance alarm conditions (poor alarm condition specificity).

Proposed State: While on the PCA infusion pump, the PATIENT is monitored with a respiration rate monitor and a pulse oximeter. If physiological parameters move outside the pre-determined range, the infusion is stopped and clinical staff is notified to examine the PATIENT and restart the infusion if appropriate. The use of two independent physiological measurements of respiratory function (oxygen saturation and respiratory rate) enables a smart algorithm to optimize sensitivity, thereby enhancing the detection of respiratory compromise while reducing nuisance alarm conditions. [23]

B.2.1.2 CConOps, safety Interlock

The patient is connected to a PCA infusion pump containing morphine sulfate, a large volume infusion pump providing a carrier line of saline, a pulse oximeter, a non-invasive blood pressure device, a respiration rate monitor and a distributed alarm system. Clinicians involved are physician, nurse, and clinical assistant. Heart rate and blood pressure, respiration rate, pain score and sedation score are collected as directed by the clinical process (e.g. using an electronic context-specific smart checklist) for set-up of a PCA pump. An intravenous (IV) line assessment is also completed. The PCA infusion pump, large volume infusion pump, and pulse oximeter are attached to the integrated system. The system queries the hospital information system for the patient's weight, age, and medication list (specifically, whether the patient is receiving sedatives or non-PCA opioids), and searches for a diagnosis of sleep apnea. The system then accesses the physician's orders from the computerized physician order entry system for dosage and rate for the PCA and large volume infusion pump, and verifies the values programmed into the infusion pump. The patient's SpO_2 (arterial oxygen saturation measured by pulse oximetry) and respiration rate are monitored continuously.

The system uses an algorithm based on weight, age, medication list, diagnoses, SpO_2 and respiration rate to determine the state of the patient. Sedation and pain scores also contribute to this algorithm. If the algorithm detects decreases in the patient's SpO_2 and/or respiration rate below the calculated or pre-set threshold, a command is sent to stop the PCA pump to prevent further drug overdose, and the system generates a respiratory distress medium priority alarm condition sent via the distributed alarm system. Furthermore, if the algorithm detects that both the SpO_2 and respiration rate indicate distress, the system generates a "severe respiratory distress" high priority alarm condition sent via the distributed alarm system.

Benefits of this new system:

Proposed State: While on the PCA infusion pump, the patient is monitored with a respiration rate monitor and a pulse oximeter. If physiological parameters move outside the pre-determined range, the infusion is stopped and clinical staff is notified to examine the patient and restart the infusion if appropriate. The use of two independent physiological measurements of respiratory function (oxygen saturation and respiratory rate) enables a smart algorithm to optimize specificity to detect respiratory compromise while reducing false positive alarm conditions and false negative alarm conditions. [22] [23] See IEC 60601-1-8 for additional information relating to alarm systems. [5]

Benefits of this new system:

a) Sensitive and specific detection of respiratory compromise prior to irreversible injury;

b) Discontinuation of medication infusion pump to slow or stop deterioration in respiratory status; and

c) Provision of early, informative, notification to the clinical staff to enable early intervention.

Risks of this new system:

d) inaccuracy of information in the physician's orders;

e) inaccuracy in the information systems;

f) inaccuracy in clinical data which contribute to the algorithm; and

g) unnecessarily stopping the infusion pump due to a false positive alarm condition for respiratory distress.

B.2.2 Synchronization with safety interlock

B.2.2.1 Clinical scenario, synchronization with safety interlock

Current State: "A 32-year-old woman had a laparoscopic cholecystectomy [gall bladder removal] performed under general anesthesia. At the surgeon's request, a plain film x-ray was shot during a cholangiogram [bile duct x-ray]. The anesthesiologist stopped the ventilator for the film. The x-ray technician was unable to remove the film because of its position beneath the table. The anesthesiologist attempted to help her, but found it difficult because the gears on the table had jammed. Finally, the x-ray was removed, and the surgical procedure recommenced. At some point, the anesthesiologist glanced at the EKG and noticed severe bradycardia. He realized he had never restarted the ventilator. (The ventilator is typically stopped for 20–60 seconds to prevent motion-induced blurring of the image.) This patient ultimately expired." [16]

Proposed State: The portable x-ray is connected to the anesthesia workstation ventilator as part of the set-up and positioning. The technician is prompted to expose the image at either inspiration or expiration per physician order. Once the technician is ready, the x-ray machine is activated, and the exposure is triggered at either inspiration or expiration. If the exposure time is calculated to be too long and the respiratory rate is too fast to permit effective synchronization, the ventilator is automatically paused (briefly) at either end-inspiration or end-expiration. The pause time is determined by the necessary exposure time, and then ventilation is automatically resumed at the pre-image respiration rate. [24]

B.2.2.2 CConOps, synchronization with safety interlock

The patient is undergoing a surgical procedure under anesthesia and is connected to an anesthesia workstation, which is part of the integrated system. The radiology technician arrives in the operating room (OR) with a portable x-ray machine, which is connected to the integrated system and positioned to take an image. The phase of the breathing cycle in which the image is to be captured (inspiration or expiration) is entered into the system by the technician. The exposure time and x-ray activation latency of the portable x-ray equipment are communicated to the integrated system. The anesthesia provider, through the user interface of the anesthesia workstation, activates an x-ray synchronization mode. In this mode the anesthesia workstation accepts a maximum of one electronic "ventilator pause" command if received within the next five minutes. The OR team are then instructed to leave the room, and the x-ray technician activates the x-ray. The integrated system determines if there is sufficient time to obtain the x-ray during the desired phase of the respiratory cycle. If so, the x-ray exposure is automatically activated at the desired phase of respiration. If not, the anesthesia workstation ventilator is paused by the system at the appropriate phase of the breathing cycle, and resumes ventilation when the image has been captured or after a pre-set time period if the image is not taken. (The ventilator automatically restarts – a resume command is not needed. This follows the safety-critical system principles of the Software Engineering Institute's Simplex Architecture. [25]) Then the OR team re-enters the OR, and the surgical procedure continues.

NOTE A similar process can be utilized in the intensive care environment with a critical care lung ventilator, or in interventional radiology for cerebrovascular imaging. [29]

Benefits of this new system:

a) Add error resistance to the x-ray procedure by eliminating the dependence on the operator (e.g. anesthesia provider) to remember to turn the ventilator back on;

b) Shorten or eliminate the period of apnea, thereby reducing potentially adverse responses to apnea; and

c) Provide the ability to synchronize x-ray exposure with inspiratory hold, without requiring anyone to be present in the x-ray exposure area to manually generate sustained inspiration.

Risks of this new system: A synchronization error could lead to x-ray exposure at an incorrect phase of respiration.

B.2.3 Process control (workflow)

B.2.3.1 Clinical scenario, process control

Current State: An elderly female was started on an IV heparin infusion for acute myocardial infarction. Daily Partial Thromboplastin Time or PTT (a blood measurement of anticoagulation) results repeatedly exceeded the therapeutic range. The heparin dose was lowered but the PTT was not repeated until the next day, when it was still high. Patient developed a retroperitoneal hematoma (internal bleeding) and died. [17]

Proposed State: The infusion pump is connected to the integrated system. Therefore, the integrated system is aware that the infusion pump is administering heparin. The system prompts the clinical staff for the required physiological measurements, generates orders for the lab to complete the PTT test, and verifies the dosage and rate of infusion with existing orders. A manual override of the pump is required in order to start the pump without the appropriate physiological measurements and orders. An override would create an appropriate notification.

B.2.3.2 CConOps, process control

The patient is attached to a large volume infusion pump with heparin solution. During the setup of the large volume infusion pump, the dosage of the heparin IV bag is verified with the computerized provider order entry system. Heart rate, blood pressure, and respiration rate are measured. An IV line assessment is completed. When the integrated system recognizes that the medication being infused is heparin, it automatically places an order for serial PTT tests. Once the laboratory information system determines the PTT, the integrated system retrieves the results and an integrated system-hosted algorithm determines whether changes to the dosage need to be made, and the clinical staff is notified.

Benefits of this new system:

a) Close the heparin administration/testing workflow loop, thereby reducing the likelihood of dosing errors; and

b) Record infusion rate setting and related physiological data for the electronic medical record and to support Quality Assurance analysis.

Risks of this system: Time-stamping of blood draws, PTT tests and reports, and heparin infusion rate changes are not accurate enough to enable safe and effective decision support.

B.2.4 Smart alarm system

B.2.4.1 Clinical scenario, smart alarm system

Current State:

Background: Cardiac (heart) surgery typically requires the use of cardiopulmonary bypass (CPB). During CPB, the CPB machine takes over both the pumping function of the heart and the ventilation function of the lung. Therefore, during CPB, the anesthesia machine ventilator is usually not needed, and is turned off to prevent unnecessary ventilation-induced lung movement that can interfere with surgery. During this period, physiological

respiratory and circulatory monitors can be turned off or their alarm signals inactivated to prevent nuisance alarm signals. At the conclusion of the CPB period, the heart resumes pumping blood, and the CPB machine pump is stopped. Lung ventilation must be resumed prior to discontinuation of CPB or non-oxygenated blood circulates and can cause organ damage. The anesthesia/surgical team has to remember to resume ventilation and manually re-start the anesthesia ventilator. Patient injuries and deaths occur when the team forgets or delays resumption of ventilation. This is a longstanding problem that continues to occur. [27] Immediately following CPB, the heart and other major organs can be especially susceptible to injury from poorly oxygenated blood.

Proposed State: The anesthesia workstation ventilator, CPB machine, and physiological monitors are connected to an integrated system. The integrated system detects the transitions on and off CPB, and provides a smart alarm to warn the OR team if CPB terminates and lung ventilation has not resumed.

B.2.4.2 CConOps, smart alarm system

An adult patient enters the OR to undergo a coronary artery bypass graft procedure under CPB. The surgeons determine that CPB is required, and the perfusion team sets up the CPB machine and connects it to an integrated system. The anesthesia workstation and physiologic monitors are already connected to the integrated system. When the system detects that CPB has begun and that ventilation has been discontinued, it queries the anesthesiologist via its user interface whether a “smart ventilation” alarm should be provided. The smart ventilation alarm would be activated if CPB flow decreases to less than 0.5 liters per minute for over 2 minutes. The smart ventilation alarm would remain engaged until CPB has stopped and ventilation has been detected continuously for 5 minutes.

Benefits of this new system: Smart, contextually aware alarm system notifies the surgical team, thereby providing sufficient time for intervention to avoid patient injury.

Risks of this new system: Intentional transient reductions in CPB flow can create nuisance alarm conditions.

B.2.5 Decision support

B.2.5.1 Clinical Scenario, decision support

Current State: The Rapid Response Team (RRT)— known also as the Medical Emergency Team — is a team of clinicians who bring rapid response critical care expertise to the patient bedside (or wherever it is needed). Activation of the RRT is usually triggered by clinical observations and a series of physiological changes. These parameters are normally documented in the patient’s chart, and the clinical staff does an RRT assessment when they perceive there is a problem with the patient (per Institute of Healthcare Improvement guidelines). Manual documentation, monitoring, and interpretation is usually ineffective in providing an early warning and intervention. “In one study, nearly 80% of hospitalized patients with cardio-respiratory arrest had abnormal vital signs documented for up to 8 hours before the actual arrest.” [26] Upon arrival at the patient’s bedside, the RRT has to sift through all available information to formulate a differential diagnosis and treatment plan, potentially delaying appropriate interventions.

Proposed State: With automatic collection and synchronization of medical device data with clinical observations, an RRT assessment can be completed automatically every time patient data is collected. Decision support can be utilized to determine whether a patient is deteriorating and to automatically notify the clinical staff or activate a Rapid Response Team, depending on the severity of the score. Early detection and intervention should reduce cardio-respiratory arrest events and near-misses. Presentation of contextually relevant patient data, and updated, interactive or “dynamic” checklists, facilitate rapid diagnosis and effective treatment.

B.2.5.2 CConOps, decision support

A patient is admitted into a non-acute care unit of the hospital. At the time of admission, clinical observations and vital signs are collected. The required values for each predetermined assessment are collected by the integrated system, which then calculates a Modified Early Warning System (MEWS) score. The MEWS score consists of respiratory rate, heart rate, systolic blood pressure, level of consciousness or sedation score, temperature, and hourly urine output. A bedside physiological monitor measures blood pressure at least every hour, at approximately the same time that the heart rate and respiration rate are collected. The nurse or clinical assistant performs a sedation assessment every 4 hours and enters the value into the integrated system. The integrated system utilizes an algorithm to calculate a MEWS score at hourly intervals. The MEWS-calculation algorithm compares these values and trends, alerts the clinical staff to changes in status and provides guidance regarding changes to the frequency of patient re-evaluation. Monitoring algorithms hosted by the integrated system automatically detect acute deterioration in patient status and alert (e.g. by pager) the RRT if necessary. Upon arrival at the patient's bedside, the integrated system presents the RRT with relevant current and historical physiological data, medication and allergy lists, and recent invasive procedures. The integrated system can present a differential diagnosis, cardiac arrest treatment algorithms, and support interventions with contextually relevant checklists.

Benefits of this new system:

a) Early warning of deteriorating patient condition; and

b) Decision support for the RRT to facilitate effective treatment.

Risks of this system:

c) Poor data quality undermines the effectiveness of the MEWS-calculation algorithm, which could lead to under- or over-alerting of the RRT; and

d) Staff dependency on the MEWS-calculation algorithm could lead to a reduction in clinical vigilance.

B.2.6 Physiological Closed Loop Control (PCLC)

B.2.6.1 Clinical scenario, PCLC

Current State: An elderly female with end-stage renal failure was given a standard insulin infusion protocol to manage her blood glucose, but no glucose was provided (either orally or intravenously). Her blood glucose dropped to 33, then rebounded to over 200 after glucose was given. [17]

Proposed State: A patient is receiving an IV insulin infusion and is having the blood glucose continuously monitored. The infusion pump rate is automatically adjusted according to the real-time blood glucose levels being measured, to maintain blood glucose values in a target range. If the patient's glucose level does not respond appropriately to the changes in insulin administration, the clinical staff is alerted.

B.2.6.2 CConOps, PCLC

A patient is receiving IV insulin via a syringe pump, glucose solution via a large-volume infusion pump, and a large-volume infusion pump of saline is serving as the intravenous carrier solution. The patient is also attached to a continuous blood glucose monitor or an intermittent glucose monitor. At the time of connecting the patient to an IV infusion, the nursing staff completes assessments of vital signs and IV line integrity. Subsequently, the large volume infusion pump (saline carrier), syringe pump (insulin), and blood glucose monitor are attached to an integrated system that queries the patient record for weight, target glucose range, typical insulin dosage range (and correction factor), and glucose responsiveness to meals (insulin-to-carbohydrate ratio). The integrated system-hosted physiologic closed-loop control (PCLC) algorithm delivers IV insulin to maintain the

blood glucose values within the clinically desired range. The clinical staff is alerted if the glucose level changes unexpectedly or outside the limits determined by the system. In order to maintain the glucose levels within the target range, the system can also change the glucose infusion rate utilizing an integrated system-hosted algorithm. The algorithm would alert the clinical staff if the glucose levels exceed a range that the algorithm can effectively manage by adjusting the insulin or glucose infusions.

Benefits of this new system:

a) facilitate maintaining blood glucose concentration in a normal range;

b) provide decision support to assist diabetes management; and

c) prevent life-threatening hypoglycemic events.

Risks of this new system:

d) Individual patients react to glucose differently and glucose management can be challenging; therefore the limits and values need to be specific to the patient; and

e) Glucose levels rise and fall somewhat slowly and somewhat unpredictably, so these factors need to be considered by the system. (These issues are addressed more generally in IEC 60601-1-10.)

B.2.7 Medical Device Plug-and-Play Interoperability (MD PnP)

B.2.7.1 Clinical scenario, MD PnP

Current State: A forty-one-year-old, 90 kg male underwent uneventful aortic valve replacement surgery and was transported to the ICU. His blood pressure (BP) was 130/70 mmHg and stable on arrival. He was placed on a lung ventilator following a routine ventilator pre-use system check. The ventilator settings were IMV = 8 breaths/min, tidal volume of 1 l, FiO_2 at 0.80, and zero positive-end expiratory pressure (PEEP). The ventilator was connected to the clinical information system so that device settings were observable at the central station and automated electronic health record documentation could be performed. Within 40 seconds of initiation of mechanical ventilation, acute hypotension developed (BP = 60/40 mmHg). Urgent evaluation by the surgical house staff focused on a presumed bleeding source or tension pneumothorax. Fortunately, evaluation by an experienced respiratory therapist and an intensivist noted the breathing system airway pressure was increasing with each breath, because the ventilator was not permitting full exhalation. The patient was immediately disconnected from the ventilator and lungs were manually ventilated with the transport ventilation system. Upon disconnection from the ventilator circuit, the patient's chest visibly decreased in diameter, with an immediate improvement in blood pressure and peripheral perfusion. The expiratory valve of the ventilator was found to be defective. A replacement critical care ventilator – produced by a different manufacturer - was connected to the patient and mechanical ventilation resumed. [39]. The first ventilator was connected to the clinical information system, but the replacement ventilator was developed by a different manufacturer, so although it had the ability to connect to the central station, it required specialized cabling and data mapping. These connections could not be completed in real time by hospital technicians, so manual documentation of ventilation was required and remote electronic observation was unavailable.

Proposed State: Both the initial and the replacement critical care ventilator conform to open interoperable connectivity standards, and may be seamlessly connected to the clinical information system. Ventilator data is also available for remote display, documentation in the EMR, and a clinical decision support system.

B.2.7.2 CConOps, MD PnP

An ICU patient is in need of mechanical lung ventilation. A sanitized ventilator is obtained from hospital inventory. The routine pre-use safety check is performed. The biomed inspection sticker is reviewed for currency. The

Plug-and-Play interface sticker is reviewed for currency. A sanitized device interface cable is obtained from ICU inventory and connected to the ventilator and to the patient headboard-mounted MD PnP data port. Following power-on self-test, the ventilator confirms connectivity to the clinical information system. (If loss of connectivity occurred, it is displayed by the ventilator.)

Benefits of this new system:

a) ventilator data is readily available for electronic documentation, remote display, and distributed alarms to improve documentation quality and enhance clinical vigilance and diagnosis, and

b) standards-based connectivity permits all conformant ventilators in hospital inventory to be available for use in clinical settings where data connectivity is important to patient care.

Risks of this new system: Expectation of seamless connectivity might not be met if device interface software and hardware are not kept current.

Annex C
(informative)

Reference to the Essential Principals

This standard has been prepared to support the essential principles of safety and performance of INTEGRATED CLINICAL ENVIRONMENT as MEDICAL DEVICES according to ISO/TR 16142:2007. This standard is intended to be acceptable for conformity assessment purposes.

Compliance with this standard provides one means of demonstrating conformance with the specific essential principles of ISO/TR 16142:2007. Other means are possible.

Table C.1 — Correspondence between the Essential Principles and this standard

Essential Principal	Corresponding Clause/Subclause of this standard	Comments
A.1		
A.2		
A.3		
A.4		
A.5		
A.6		
A.7.1		
A.7.2		
A.7.3		
A.7.4		
A.7.5		
A.7.6		
A.8.1		
A.8.1.1		
A.8.1.2		
A.8.2		
A.8.3		
A.8.4		
A.8.5		
A.8.6		
A.9.1		
A.9.2		

Essential Principal	Corresponding Clause/Subclause of this standard	Comments
A.9.3		
A.10.1		
A.10.2		
A.10.3		
A.11.1		
A.11.2.1		
A.11.2.2		
A.11.3		
A.11.4		
A.11.5.1		
A.11.5.2		
A.11.5.3		
A.12.1		
A.12.2		
A.12.3		
A.12.4		
A.12.5		
A.12.6		
A.12.7.1		
A.12.7.2		
A.12.7.3		
A.12.7.4		
A.12.7.5		
A.12.8.1		
A.12.8.2		
A.12.8.3		
A.13.1		
A.14.1		

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Terminology – Alphabetized index of defined terms