



F2761-09(2013)

**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.

This ASTM standard was prepared by ASTM Committee F29, *Anaesthetic and Respiratory Equipment*, Subcommittee F29.21, *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.^{[8],[9],[28],[37]}

This is the first edition.

F2761 is expected to be 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 F2761, 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]

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.

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*

ISO 11135, *Medical Devices – Validation and routine control of ethylene oxide sterilization*

ISO 11137, *Sterilization of healthcare products - Requirements for validation and routine control – Radiation sterilization*

ISO 11607, *Packaging for terminally sterilized medical devices*

ISO 11990, *Optics and optical instruments — Lasers and laser-related equipment — Determination of laser resistance of tracheal tube shafts*

ISO 11991, *Guidance on airway management during laser surgery of upper airway*

ISO 14155-1, *Clinical investigation of medical devices for human subjects -- Part 1: General requirements*

ISO 14155-2, *Clinical investigation of medical devices for human subjects -- Part 2: Clinical investigation plans*

ISO 14408, *Tracheal tubes and related treatments designed for resistance to ignition by a laser - Requirements for marking, labeling and accompanying information*

ISO 14971, *Medical devices – Applications of risk management to medical devices*
Terms and definitions

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 with ISO 14971 and which are connected with their intended application in normal condition and single fault condition.

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.

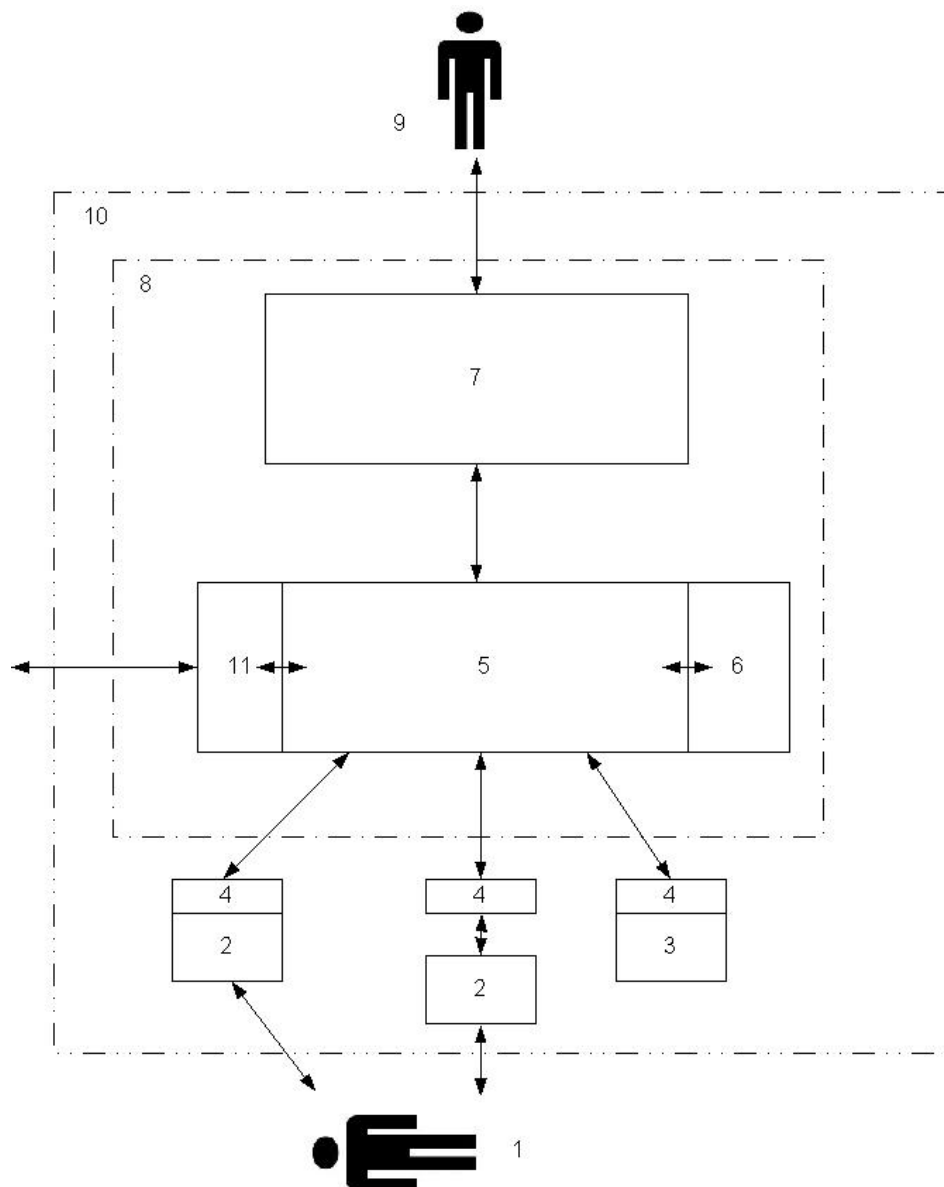
This standard introduces a specific conceptual functional model for defining the ICE. The model defines separate functions that comprise the ICE. In order to support essential safety this standard allocates requirements to defined functions of the ICE. This allows each MANUFACTURER to provide the functions 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:

1. 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);
2. ICE NETWORK CONTROLLER and ICE SUPERVISOR deployed independently (Figure 1, items 5 and 7 as separate equipment);
3. 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.

4. 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.

5. 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:

1. 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
2. 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