

**ASTM final F-2761**

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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**

*Élément introductif — Élément central — Partie 1: Titre de la partie*



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## 53 Foreword

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

56 ASTM 2761 was prepared by ASTM Committee F-29, *Anaesthetic and Respiratory Equipment*, Subcommittee  
57 21, *Devices in the integrated clinical environment*. This work is based in part on concepts developed within the  
58 CIMIT Program<sup>[8]</sup> on Interoperability and the Massachusetts General Hospital program on Medical Device “Plug-  
59 and-Play” Interoperability (“MD PnP” program, founded 2004) with information disseminated through  
60 publications, workshops, and website.<sup>[9] [28],[37]</sup>

61 This is the first edition.

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

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

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

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

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

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

80 In this standard, the following print types are used:

81 — Requirements and definitions: roman type.

82 — Test specifications: italic type.

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

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

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

38 For the purposes of this standard, the auxiliary verb:

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

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

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

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

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

41



102 **Introduction**

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

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

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

118



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

123 **1 \* Scope**

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

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

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

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

137 **2 Normative references**

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

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

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

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

49 IEC 80001:—<sup>1)</sup>, *Application of risk management for IT-networks incorporating medical devices*

### 50 **3 Terms and definitions**

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

#### 53 **3.1**

##### 54 **BASIC SAFETY**

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

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

#### 58 **3.2**

##### 59 **CEC**

##### 60 **CLINICAL ENVIRONMENT COORDINATOR**

61 equipment, remote from the INTEGRATED CLINICAL ENVIRONMENT, that can control one or more INTEGRATED  
62 CLINICAL ENVIRONMENTS

63 EXAMPLE 1 Remote OPERATOR-interface for an ICE SUPERVISOR.

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

#### 65 **3.3**

##### 66 **\* DEVICE MODEL**

67 representation of the capabilities of ICE-COMPATIBLE EQUIPMENT that includes the information needed to  
68 qualitatively and quantitatively describe, control and monitor its operation

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

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

#### 71 **3.4**

##### 72 **ESSENTIAL PERFORMANCE**

73 performance necessary to achieve freedom from unacceptable RISK

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

76 [IEC 60601-1:2005, definition 3.27]

#### 77 **3.5**

##### 78 **FULLY COMPLIANT**

79 type of ICE EQUIPMENT INTERFACE where the DEVICE MODEL is exported through the ICE EQUIPMENT INTERFACE to  
80 the ICE NETWORK CONTROLLER

---

1) To be published.

181 **3.6**

182 **\* ICE**

183 **INTEGRATED CLINICAL ENVIRONMENT**

184 environment that combines interoperable heterogeneous MEDICAL DEVICES and other equipment integrated to  
185 create a medical system for the care of a single high acuity PATIENT

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

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

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

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

194 **3.7**

195 **ICE-COMPATIBLE EQUIPMENT**

196 MEDICAL DEVICE or other electrical equipment with an ICE EQUIPMENT INTERFACE

197 **3.8**

198 **ICE EQUIPMENT INTERFACE**

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

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

202 **3.9**

203 **ICE NETWORK CONTROLLER**

204 part of an ICE that provides communication between ICE-COMPATIBLE EQUIPMENT and the rest of the ICE, using the  
205 DEVICE model

206 **3.10**

207 **ICE SUPERVISOR**

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

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

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

213 **3.11**

214 **INTENDED USE**

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

217 [IEC 14971:2007, definition 2.5, modified]

218 **3.12**

219 **MANUFACTURER**

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

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

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

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

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

### 32 3.13

#### 33 MEDICAL DEVICE

34 any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software,  
35 material or other similar or related article, intended by the MANUFACTURER to be used, alone or in combination,  
36 for human beings for one or more of the specific purpose(s) of

- 37 - diagnosis, prevention, monitoring, treatment or alleviation of disease,
- 38 - diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- 39 - investigation, replacement, modification, or support of the anatomy or of a physiological process,
- 40 - supporting or sustaining life,
- 41 - control of conception,
- 42 - disinfection of MEDICAL DEVICES,
- 43 - providing information for medical purposes by means of *in vitro* examination of specimens derived from the  
44 human body,  
45 and which does not achieve its primary intended action in or on the human body by pharmacological,  
46 immunological or metabolic means, but which can be assisted in its function by such means

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

48 [ISO 14971:2007, definition 2.9]

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

### 50 3.14

#### 51 MODEL COMPLIANT

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

### 54 3.15

#### 55 OPERATOR

56 person handling equipment

57 [IEC 60601-1:2005, definition 3.73]

### 58 3.16

#### 59 PATIENT

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

31 [IEC 60601-1:2005, definition 3.76]

262 **3.17**

263 **RESPONSIBLE ORGANIZATION**

264 entity accountable for the use and maintenance of a MEDICAL DEVICE or a medical system

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

267 NOTE 2 Education and training is included in “use.”

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

## 269 **4 \*ICE conceptual functional model**

### 270 **4.1 Overview**

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

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

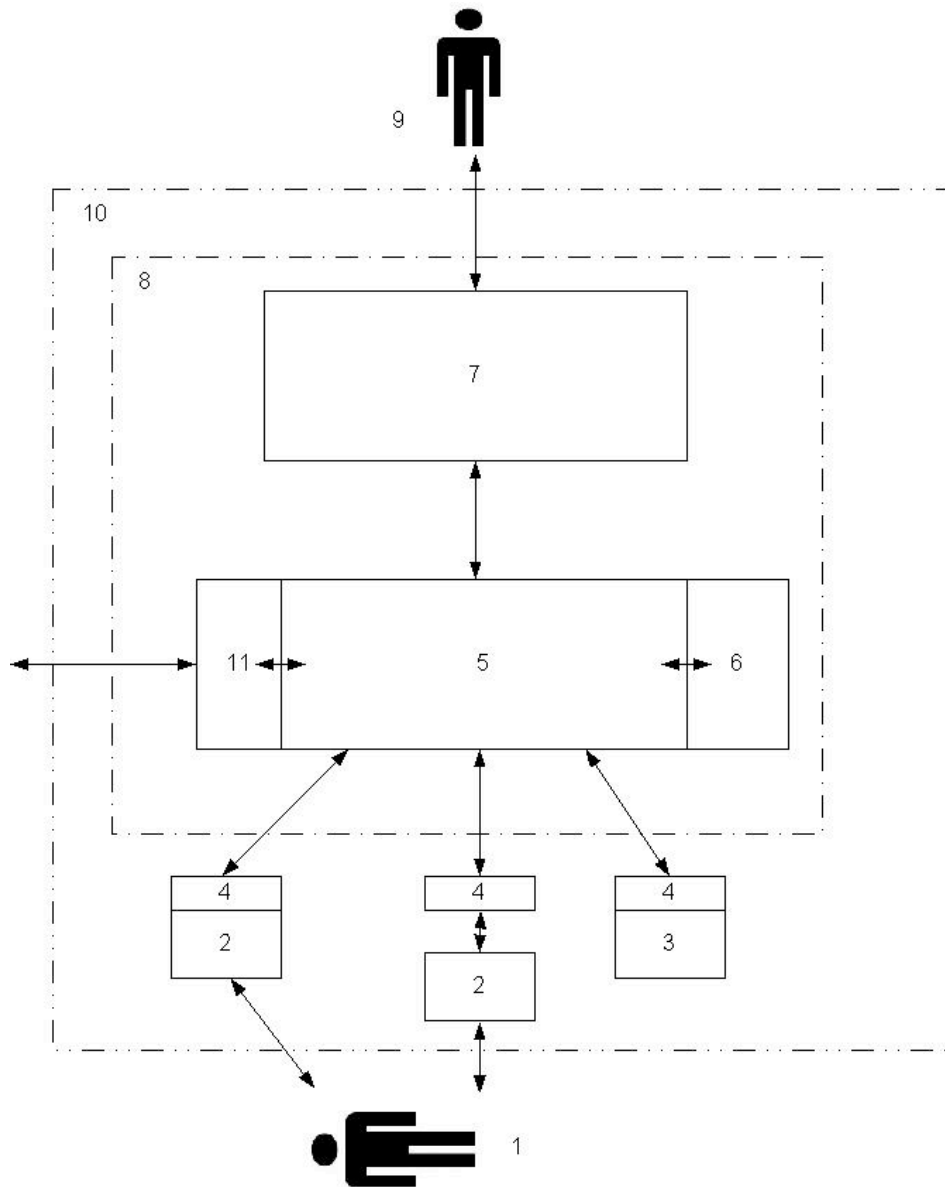
280 The functional model includes an ICE NETWORK CONTROLLER, as defined in 3.9, one or more  
281 ICE EQUIPMENT INTERFACES, as defined in 3.8, and an ICE SUPERVISOR, as defined in 3.10, which allows the  
282 RESPONSIBLE ORGANIZATION to manage the RISK of integrating a collection of Information and Communication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

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

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

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

289



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**



302 ICE deployments may include the following physical configurations:

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

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

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

308 EXAMPLE 1 A ventilator that includes an ICE manager.

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

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

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

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

## 315 4.2 ICE NETWORK CONTROLLER

### 316 4.2.1 \* General

317 The ICE NETWORK CONTROLLER is responsible for:

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

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

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

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

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

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

### 329 4.2.2 ICE NETWORK CONTROLLER interface

330 A port on the ICE NETWORK CONTROLLER provides communication to an ICE EQUIPMENT INTERFACE, covering layers  
331 1 to 4 of the ISO OSI reference model. <sup>[1]</sup> A key objective is to make the implementation of the upper layers of  
332 the communication stack of the ICE NETWORK CONTROLLER independent of the particular  
333 ICE EQUIPMENT INTERFACE.

334 An ICE NETWORK CONTROLLER shall provide:

335 a) Communication ports to connect to ICE EQUIPMENT INTERFACES.

336 EXAMPLE 1 an Ethernet port

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

38 EXAMPLE 3 a universal serial bus (USB) port

39 EXAMPLE 4 an RS-232 port

40 EXAMPLE 5 a controller area network (CAN) port

41 EXAMPLE 6 an IEEE 802.11 port

42 EXAMPLE 7 an IEEE 802.15.1 (Bluetooth) port

43 EXAMPLE 8 an IEEE 802.15.4 (ZigBee) port

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

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

47 *Check compliance by inspection.*

#### 48 **4.2.3 \* External interface**

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

- 51 a) Connection to the professional healthcare facility network backbone;
- 52 b) Connection to the public switched network;
- 53 c) Connection to the internet;

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

- 56 d) Connection to a CLINICAL ENVIRONMENT COORDINATOR;
- 57 e) Connection via a CLINICAL ENVIRONMENT COORDINATOR by delegation or proxy.

58 NOTE A CLINICAL ENVIRONMENT COORDINATOR supports multiple INTEGRATED CLINICAL ENVIRONMENTS.

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

62 The technical description shall include a reference to IEC 80001:—<sup>2</sup> and the necessity of the RESPONSIBLE  
63 ORGANIZATION to perform RISK MANAGEMENT, including the qualification test for the equipment, prior to placing the  
64 system into service.

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

---

<sup>2</sup> To be published.

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

#### 368 **4.2.4 \* Forensic data logging**

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

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

#### 374 **4.3 \*ICE SUPERVISOR**

375 The ICE SUPERVISOR is responsible for:

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

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

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

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

#### 383 **4.4 \* ICE EQUIPMENT INTERFACE**

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

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

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

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

### 390 **5 General requirements**

#### 391 **5.1 RISK MANAGEMENT PROCESS**

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

394 In applying ISO 14971:2007:

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

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

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

41 — *established a RISK MANAGEMENT PROCESS;*

42 — *established acceptable levels of RISK; and*

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

## 45 **5.2 \* ICE EQUIPMENT INTERFACE qualification test**

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

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

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

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

## 16 **5.3 Software**

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

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

## 21 **5.4 Communication management**

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

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

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

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

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

---

3) To be published.

- 432 d) failures caused by erroneous commands;
- 433 e) failures caused by receiving and processing erroneous data or commands; and
- 434 f) failures caused by not adhering to the non-functional requirements of the communication specification.

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

#### 436 **5.5 ALARM SYSTEM**

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

438 In applying IEC 60601-1-8:2006:

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

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

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

13 **Annex A**  
14 **(informative)**

15 **Guidance and rationale**  
16

17 **A.1 General guidance**

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

23 **A.2 Rationale and guidance for particular clauses and subclauses**

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

26 **Clause 1 Scope**

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

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

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

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

500 **Definition 3.3 DEVICE MODEL**

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

510 The DEVICE MODEL represents the characteristics of the data flowing in and out of the MEDICAL DEVICE through the  
511 DEVICE MODEL. It describes, in machine and human readable format, the concept that a data parameter  
512 represents (e.g., blood pressure, O<sub>2</sub> concentration, pulse rate), the units of representation (e.g., mmHg,  
513 beats/min), and the bit encoding of the parameter (e.g., 16-bit fixed point, 32-bit floating point). Data parameters  
514 can represent physiological measurements of the PATIENT, time of measurement, state of the MEDICAL DEVICE,  
515 etc. The DEVICE MODEL also includes a state space representation of the MEDICAL DEVICE. The ICE EQUIPMENT  
516 INTERFACE of ICE-COMPATIBLE EQUIPMENT can be either FULLY COMPLIANT or MODEL COMPLIANT, i.e., the DEVICE  
517 MODEL is communicated through the ICE EQUIPMENT INTERFACE or is provided by other means. The  
518 MANUFACTURER chooses the capabilities that are exposed through the ICE EQUIPMENT INTERFACE.

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

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

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

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

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

### 48 **Definition 3.6 INTEGRATED CLINICAL ENVIRONMENT (ICE)**

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

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

31 NOTE The PATIENT can be the OPERATOR.

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



567 **Subclause 4.2 ICE NETWORK CONTROLLER**

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

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

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

- 588 a) The physical medium of information transfer, including connectors for wired communications channels  
589 (layer 1 of the Open Systems Interconnection or OSI communication model);
- 590 b) The protocols used for data transport on that medium (layers 2-4 of the Open Systems Interconnection or  
591 OSI model)—the communications stack;
- 592 c) The semantics of the data exchanged between the ICE NETWORK CONTROLLER and a MEDICAL DEVICE;
- 593 d) The application level protocols between the ICE NETWORK CONTROLLER and a MEDICAL DEVICE.

594 Usually the communication medium and stack are bundled to produce a data transport pipe, e.g., TCP/IP<sup>6</sup> over  
595 Ethernet. While there are various flavors of Ethernet, the higher speed versions are generally compatible with  
596 the lower speed versions. Backwards compatibility is usually retained as these transport pipes evolve their  
597 operating speeds. There are a small number of practical choices for a MEDICAL DEVICE that have been, or are  
598 likely to be used in the future, including TCP/IP over Ethernet (including Powerlink Ethernet), USB, RS-232,  
599 802.11 wireless variations, and CAN. To implement one of these pipes, an ICE NETWORK CONTROLLER needs a  
600 hardware interface and drivers (the stack protocol handlers) for that interface. One can envision an  
601 ICE NETWORK CONTROLLER as a PC/Workstation with slots to plug in the appropriate interfaces. Older  
602 ICE NETWORK CONTROLLER implementations could be updated with the addition of an I/O card and the stack  
603 drivers that come with it.

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

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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.

642 **Subclause 4.2.4 Forensic data logging**

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

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

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

- 653 a) ICE-COMPATIBLE EQUIPMENT technical variables and TECHNICAL ALARM CONDITIONS available to the  
654 ICE NETWORK CONTROLLER;
- 655 b) PATIENT physiological variables and PHYSIOLOGICAL ALARM CONDITIONS from ICE-COMPATIBLE EQUIPMENT  
656 available to the ICE NETWORK CONTROLLER;
- 657 c) ICE NETWORK CONTROLLER commands to ICE-COMPATIBLE EQUIPMENT;
- 658 d) ICE NETWORK CONTROLLER status;
- 659 e) Any other significant events and errors.

660 EXAMPLE Storage of any ALARM SIGNAL inactivation state.

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

- 662 f) OPERATOR commands to the ICE NETWORK CONTROLLER;
- 663 g) ICE SUPERVISOR status;
- 664 h) OPERATOR commands to the ICE SUPERVISOR;
- 665 i) Anomalies in ICE determined by the ICE SUPERVISOR;
- 666 j) The state of workflow plan execution and deviations from nominal of all variables per the workflow plan;
- 667 k) External data consumed and external commands and controls.

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

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

671 **Subclause 4.3 ICE SUPERVISOR**

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

- 674 — Provide safety interlocks;

- 75 — Distribute integrated ALARM CONDITIONS to relevant OPERATORS;
- 76 — Provide context-aware clinical decision support;
- 77 — Set command input variables of other MEDICAL DEVICES, per OPERATOR-defined, context-appropriate rules, in  
78 order to manage their operation;
- 79 — Assess the readiness of MEDICAL DEVICES to support specified functions or clinical workflow;
- 30 — Combine ALARM CONDITIONS from multiple MEDICAL DEVICES for integrated OPERATOR display, notification and  
31 reporting;
- 32 — Utilize the data available from, and control the operation of, each MEDICAL DEVICE (as characterized by the  
33 DEVICE MODEL provided by each MEDICAL DEVICE) in the clinical environment to the extent permitted by each  
34 MEDICAL DEVICE;
- 35 — Perform automated record keeping;
- 36 — Support remote access and control of MEDICAL DEVICES.

#### 37 **Subclause 4.4 ICE EQUIPMENT INTERFACE**

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

- 30 a) Common interconnection hardware between the ICE Network Controller the Medical Device (the “ICE  
31 equipment interface port”) with services providing data exchange capabilities;
- 32 b) A common set of communication protocols, typically consisting of an information model, a service model  
33 and a set of protocol data structures mapping the models to messages that are exchanged between the ICE  
34 NETWORK CONTROLLER and the ICE-COMPATIBLE EQUIPMENT; and
- 35 c) A set of semantics (a terminology) to uniquely identify concepts of represented data, such as  
36 measurements and controls.

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

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

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

- 47 - ISO 8802/IEEE 802 series<sup>[2]</sup>

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

- 11 - ISO/IEEE P11073 series for Standard for Medical Device Communications<sup>[3]</sup>

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

713 - IHE PCD Profile<sup>[14]</sup>

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.

23 **Annex B**  
24 (informative)

25 **Clinical context and clinical scenarios**  
26

27 **B.1 Purpose and introduction**

28 **B.1.1 Purpose**

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

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

37 **B.1.2 Methodology**

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

40 Typical instructions and background for participants:

41 *Assume that the integrated medical system provides seamless connectivity of medical devices to*  
42 *allow communication (e.g. remote data display, population of the electronic medical record, etc.)*  
43 *and integration of medical devices with control functions (e.g. control of infusion pumps from the*  
44 *anesthesia workstation, implementation of “safety interlocks” to stop an infusion at a pre-*  
45 *determined blood pressure value or to prevent intra-abdominal CO<sub>2</sub> insufflation if the heart rate and*  
46 *blood pressure are unmonitored, etc.).*

47 *Assume that there are no technical, economic, legal or regulatory obstacles to deploying a*  
48 *comprehensive system. Define the high-level clinical needs without specifying the details of the*  
49 *technical specifications.*

- 50 a) *Which clinical challenges exist today that could be solved by the proposed system?*
- 51 b) *Which obstacles to safety, efficiency, and teamwork could be reduced or eliminated by the*  
52 *proposed system?*
- 53 c) *How would this approach affect the practice environment, both clinically and from a*  
54 *business/process perspective?*
- 55 d) *What risks can be introduced by an integrated medical system, and how could they be*  
56 *mitigated?*

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

### 759 **B.1.3 Clinical scenario**

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

- 763 a) the Current State typically describes an adverse event that has occurred to a patient;
- 764 b) the Proposed State is a brief illustration of the improvement in safety and effectiveness obtained by applying  
765 an integrated solution.

### 766 **B.1.4 Clinical concept of operations (CConOps)**

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

769 This description provides details of:

- 770 — The type of equipment utilized;
- 771 — The clinical processes required;
- 772 — The type or category of clinical staff;
- 773     EXAMPLES   Surgeon, intensivist, anesthesia provider, chief nurse, nursing assistant, respiratory therapist.
- 774 — Potential changes or new/novel equipment or workflow that does not exist today but that could improve the  
775 process (optional);
- 776 — Benefits of the proposed process; and
- 777 — Risk analysis of the proposed process.

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

## 780 **B.2 Clinical Examples**

### 781 **B.2.1 Safety Interlocks**

#### 782 **B.2.1.1 Clinical scenario, safety Interlock**

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

case by providers implicated a PCA overdose.”<sup>[10]</sup> 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.<sup>[23]</sup>

#### **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<sub>2</sub> (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<sub>2</sub> 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<sub>2</sub> 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<sub>2</sub> 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.<sup>[22] [23]</sup> See IEC 60601-1-8 for additional information relating to alarm systems.<sup>[5]</sup>

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;



- 833 e) inaccuracy in the information systems;
- 834 f) inaccuracy in clinical data which contribute to the algorithm; and
- 835 g) unnecessarily stopping the infusion pump due to a false positive alarm condition for respiratory distress.

## 836 **B.2.2 Synchronization with safety interlock**

### 837 **B.2.2.1 Clinical scenario, synchronization with safety interlock**

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

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

### 853 **B.2.2.2 CConOps, synchronization with safety interlock**

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

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

872 Benefits of this new system:

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

- 75 b) Shorten or eliminate the period of apnea, thereby reducing potentially adverse responses to apnea; and
- 76 c) Provide the ability to synchronize x-ray exposure with inspiratory hold, without requiring anyone to be  
77 present in the x-ray exposure area to manually generate sustained inspiration.

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

### 30 **B.2.3 Process control (workflow)**

#### 31 **B.2.3.1 Clinical scenario, process control**

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

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

#### 31 **B.2.3.2 CConOps, process control**

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

39 Benefits of this new system:

- 40 a) Close the heparin administration/testing workflow loop, thereby reducing the likelihood of dosing errors; and
- 41 b) Record infusion rate setting and related physiological data for the electronic medical record and to support  
42 Quality Assurance analysis.

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

### 45 **B.2.4 Smart alarm system**

#### 46 **B.2.4.1 Clinical scenario, smart alarm system**

47 Current State:

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

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

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

#### 923 **B.2.4.2 CConOps, smart alarm system**

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

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

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

#### 935 **B.2.5 Decision support**

##### 936 **B.2.5.1 Clinical Scenario, decision support**

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

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

### 53 **B.2.5.2 CConOps, decision support**

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

69 Benefits of this new system:

- 70 a) Early warning of deteriorating patient condition; and
- 71 b) Decision support for the RRT to facilitate effective treatment.

72 Risks of this system:

- 73 c) Poor data quality undermines the effectiveness of the MEWS-calculation algorithm, which could lead to  
74 under- or over-alerting of the RRT; and
- 75 d) Staff dependency on the MEWS-calculation algorithm could lead to a reduction in clinical vigilance.

### 76 **B.2.6 Physiological Closed Loop Control (PCLC)**

#### 77 **B.2.6.1 Clinical scenario, PCLC**

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

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

#### 85 **B.2.6.2 CConOps, PCLC**

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

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

999 Benefits of this new system:

1000 a) facilitate maintaining blood glucose concentration in a normal range;

1001 b) provide decision support to assist diabetes management; and

1002 c) prevent life-threatening hypoglycemic events.

1003 Risks of this new system:

1004 d) Individual patients react to glucose differently and glucose management can be challenging; therefore the  
1005 limits and values need to be specific to the patient; and

1006 e) Glucose levels rise and fall somewhat slowly and somewhat unpredictably, so these factors need to be  
1007 considered by the system. (These issues are addressed more generally in IEC 60601-1-10.)

## 1008 **B.2.7 Medical Device Plug-and-Play Interoperability (MD PnP)**

### 1009 **B.2.7.1 Clinical scenario, MD PnP**

1010 Current State: A forty-one-year-old, 90 kg male underwent uneventful aortic valve replacement surgery and was  
1011 transported to the ICU. His blood pressure (BP) was 130/70 mmHg and stable on arrival. He was placed on a  
1012 lung ventilator following a routine ventilator pre-use system check. The ventilator settings were IMV = 8  
1013 breaths/min, tidal volume of 1 l, FiO<sub>2</sub> at 0.80, and zero positive-end expiratory pressure (PEEP). The ventilator  
1014 was connected to the clinical information system so that device settings were observable at the central station  
1015 and automated electronic health record documentation could be performed. Within 40 seconds of initiation of  
1016 mechanical ventilation, acute hypotension developed (BP = 60/40 mmHg). Urgent evaluation by the surgical  
1017 house staff focused on a presumed bleeding source or tension pneumothorax. Fortunately, evaluation by an  
1018 experienced respiratory therapist and an intensivist noted the breathing system airway pressure was increasing  
1019 with each breath, because the ventilator was not permitting full exhalation. The patient was immediately  
1020 disconnected from the ventilator and lungs were manually ventilated with the transport ventilation system. Upon  
1021 disconnection from the ventilator circuit, the patient's chest visibly decreased in diameter, with an immediate  
1022 improvement in blood pressure and peripheral perfusion. The expiratory valve of the ventilator was found to be  
1023 defective. A replacement critical care ventilator – produced by a different manufacturer – was connected to the  
1024 patient and mechanical ventilation resumed.<sup>[39]</sup> The first ventilator was connected to the clinical information  
1025 system, but the replacement ventilator was developed by a different manufacturer, so although it had the ability  
1026 to connect to the central station, it required specialized cabling and data mapping. These connections could not  
1027 be completed in real time by hospital technicians, so manual documentation of ventilation was required and  
1028 remote electronic observation was unavailable.

1029 Proposed State: Both the initial and the replacement critical care ventilator conform to open interoperable  
1030 connectivity standards, and may be seamlessly connected to the clinical information system. Ventilator data is  
1031 also available for remote display, documentation in the EMR, and a clinical decision support system.

### 1032 **B.2.7.2 CConOps, MD PnP**

1033 An ICU patient is in need of mechanical lung ventilation. A sanitized ventilator is obtained from hospital inventory.  
1034 The routine pre-use safety check is performed. The biomed inspection sticker is reviewed for currency. The

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

39 Benefits of this new system:

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

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

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

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**Annex C**  
**(informative)**

**Reference to the Essential Principles**

1051 This standard has been prepared to support the essential principles of safety and performance of INTEGRATED  
1052 CLINICAL ENVIRONMENT as MEDICAL DEVICES according to ISO/TR 16142:2007. This standard is intended to be  
1053 acceptable for conformity assessment purposes.

1054 Compliance with this standard provides one means of demonstrating conformance with the specific essential  
1055 principles of ISO/TR 16142:2007. Other means are possible.

1056 **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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## Bibliography

- 1060 [1] ISO 7498-1:1994, *Information technology - Open systems interconnection - Basic reference model*
- 1061 [2] ISO 8802 (series), *Information technology — Telecommunications and information exchange between*  
1062 *systems -- Local and metropolitan area networks — Specific requirements*
- 1063 [3] ISO 11073 (series), *Health informatics — Point-of-care medical device communication*
- 1064 [4] IEC 60601-1, *Medical electrical equipment — Part 1: General requirements for basic safety and*  
1065 *essential performance*
- 1066 [5] IEC 60601-1-8, *Medical electrical equipment — Part 1-8: General requirements for basic safety and*  
1067 *essential performance – Collateral Standard: General requirements, tests and guidance for alarm*  
1068 *systems in medical electrical equipment and medical electrical systems*
- 1069 [6] IEC 60601-1-10, *Medical electrical equipment — Part 1-10: General requirements for basic safety and*  
1070 *essential performance — Collateral Standard: Requirements for the development of physiologic closed-*  
1071 *loop controllers*
- 1072 [7] IEC 62366:2007, *Medical devices — application of usability engineering to medical devices*
- 1073 [8] CIMIT, Center for Integration of Medicine and Innovative Technology <sup>7</sup>
- 1074 [9] CSDL-422944:D.1, *Draft Standard for an Integrated Clinical Environment Manager (ICEMan)*, Prepared  
1075 for the MD PnP Program by The Charles Stark Draper Laboratory, Inc., June 1, 2006
- 1076 [10] AHRQ. (n.d.). Web M&M. Web M&M Morbidity & Mortality Rounds on the Web:  
1077 <http://webmm.ahrq.gov/caseArchive.aspx>, Verified July 17, 2008.
- 1078 [11] *Society Endorsement of interoperability*, [http://www.mdnp.org/Endorsements\\_of\\_Interop.html](http://www.mdnp.org/Endorsements_of_Interop.html), verified  
1079 July 25, 2008
- 1080 [12] Global Harmonization Task Force (GHTF) — Study Group 1 (SG1), *Information Document Concerning*  
1081 *the Definition of the Term “Medical Device”*, N29R16:2005
- 1082 [13] IEEE 1073:1996, *IEEE Standard for Medical Device Communications—Overview and Framework*
- 1083 [14] IHE Technical Frameworks, *Patient Care Devices Technical Framework* <sup>8</sup>
- 1084 [15] Institute of Healthcare Improvement. (n.d.). Establish a Rapid Response Team. Retrieved July 16, 2008
- 1085 [16] LOFSKY, A.S., Turn Your Alarms On. *APSF Newsletter*, Winter 2005, p. 43. Verified August 28, 2008
- 1086 [17] NUCKOLS, T.K. Programmable Infusion Pumps in ICUs: An Analysis of Corresponding Adverse Drug  
1087 Events. *Journal of General Internal Medicine*, 2007 pp. 41-45

---

7) <http://www.cimit.org>, accessed February 2, 2009

8) <http://www.ihe.net>, accessed November 1, 2009

- 38 [18] REID, P., et al, *Building a Better Delivery System: A New Engineering/Health Care Partnership*, The  
39 National Academies Press, Washington, DC, 2005
- 30 [19] Proceedings of the Joint Workshop on High-Confidence Medical Devices, Software, and Systems and  
31 Medical Device Plug-and-Play Interoperability (HCMDSS / MD PnP 2007). IEEE Computer Society  
32 Press, 2008.
- 33 [20] Medical Device Connectivity for Improving Safety and Efficiency. American Society of Anesthesiologists  
34 Newsletter. Park Ridge, IL: American Society of Anesthesiologists. 2006.
- 35 [21] Eliciting Clinical Requirements for the Medical Device Plug-and-Play (MD PnP) Interoperability Program.  
36 *Anesth Analg.* 2006;102:S1-54.
- 37 [22] Improving the Safety of Patient Controlled Analgesia Infusions with Safety Interlocks and Closed-Loop  
38 Control. In: Proceedings of the Joint Workshop on High-Confidence Medical Devices, Software, and  
39 Systems and Medical Device Plug-and-Play Interoperability (HCMDSS / MD PnP 2007), IEEE Computer  
40 Society Press, 2008. pp. 149-150.
- 41 [23] American Society of Anesthesiologists 2007 annual meeting Scientific Exhibit "Improving the Safety of  
42 PCA Opioid Infusions by Integrating Patient Monitors and Infusion Pumps".  
43 <http://www.asahq.org/Newsletters/2008/01-08/rosenberg01-08.html>,  
44 [http://mdpnp.org/uploads/ASA\\_2007\\_MD\\_PnP\\_Poster1\\_PCA.pdf](http://mdpnp.org/uploads/ASA_2007_MD_PnP_Poster1_PCA.pdf),  
45 [http://mdpnp.org/uploads/ASA\\_2007\\_MD\\_PnP\\_Poster2.pdf](http://mdpnp.org/uploads/ASA_2007_MD_PnP_Poster2.pdf)
- 46 [24] Use Case Demonstration: X-Ray/Ventilator. In: Proceedings of the Joint Workshop on High-Confidence  
47 Medical Devices, Software, and Systems and Medical Device Plug-and-Play Interoperability (HCMDSS /  
48 MD PnP 2007), 149-150. IEEE Computer Society Press, 2008. P. 160.
- 49 [25] SEI Simplex Architecture description in <http://www.sei.cmu.edu/simplex/>, verified November 11, 2008.
- 50 [26] Advanced Cardiac Life Support provider manual, American Heart Association 2006, p. 17.
- 51 [27] Adverse Anesthetic Outcomes Arising from Gas Delivery Equipment: A Closed Claims Analysis.  
52 *Anesthesiology.* 87(4):741-748, October 1997.
- 53 [28] Getting Connected for Patient Safety: How Medical Device "Plug-and-Play" Interoperability Can Make a  
54 Difference. *Patient Safety & Quality Healthcare* 5:1, Jan-Feb 2008.
- 55 [29] Synchronization of Radiograph Film Exposure with the Inspiratory Pause Effect on the Appearance of  
56 Bedside Chest Radiographs in Mechanically Ventilated Patients. *American J of Resp and Crit Care Med*,  
57 V160, p2067, 1999.
- 58 [30] Chiao J.C. et al, Metrology and Standards Needs for Some Categories of Medical Devices. *J. Res. Natl.*  
59 *Inst. Stand. Technol.* V113, No2, 121-129, 2008.
- 60 [31] <http://www.ghtf.org>
- 61 [32] [http://www.ihe.net/Technical\\_Framework/index.cfm#pcd](http://www.ihe.net/Technical_Framework/index.cfm#pcd)
- 62 [33] Interoperability of Medical Devices, World Federation of Societies of Anaesthesiologists  
63 <http://www.anaesthesiologists.org/en/latest/interoperability-of-medical-devices.html>, verified November  
64 11, 2008
- 65 [34] APSF Endorses Medical Device Interoperability, *ASPF*,  
66 <http://www.apsf.org/initiatives/interoperability.mspx>, verified Sept 25, 2008

- 1127 [35] American Medical Association resolution 519 endorsing medical device interoperability, [http://www.ama-](http://www.ama-assn.org/ama1/pub/upload/mm/475/a-09-ref-comm-e-annotated.pdf)  
1128 [assn.org/ama1/pub/upload/mm/475/a-09-ref-comm-e-annotated.pdf](http://www.ama-assn.org/ama1/pub/upload/mm/475/a-09-ref-comm-e-annotated.pdf), accessed December 9, 2009.
- 1129 [36] American Society of Anaesthesiologists statement on the interoperability of medical devices,  
1130 <http://www.asahq.org/publicationsAndServices/standards/50.pdf>, accessed December 9, 2009.
- 1131 [37] CIMIT/MGH Medical Device Interoperability Program official website: [www.mdnp.org](http://www.mdnp.org)
- 1132 [38] Schrenker, R, Cooper, T, Building the foundation for medical device plug-and-play interoperability, *Med.*  
1133 *Electron. Manuf.* (2001) **10**-16.
- 1134 [39] PRIELIPP, R.C., et.al., Ventilator Failure in the ICU: Déjà Vu All Over Again. *Anesthesia Patient*  
1135 *Foundation Newsletter*. Wilmington, DE, **13**(3), 1998,  
1136 [http://www.apsf.org/resource\\_center/newsletter/1998/fall/09vent.html](http://www.apsf.org/resource_center/newsletter/1998/fall/09vent.html), verified Nov. 11, 2008
- 1137

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