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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

Contents

Foreword

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

This ASTM standard was prepared by ASTM Committee F29, *Anaesthetic and Respiratory Equipment*, Subcommittee F29.21, *Devices in the Integrated Clinical Environment*. This work is based in part on concepts developed within the CIMIT Program [8] on Interoperability and the Massachusetts General Hospital program on Medical Device "Plug-and-Play" Interoperability ("MD PnP" program, founded 2004) with information disseminated through publications, workshops, and website.[8],[9], [28],[37]

This is the first edition.

F2761 is expected to be part of a series of standards, under the general title Medical Devices and Medical Systems — Essential principles of safety and performance for equipment comprising the patient-centric integrated clinical environment (ICE):

- *ASTM F2761, Medical Devices and Medical Systems — Essential principles of safety and performance for equipment comprising the patient-centric integrated clinical environment (ICE) Part 1: General requirements and conceptual model (this standard)*

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

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

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

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

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

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

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

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