

These definitions and framework have been published in Annex B of ASTM standard F2761-09 “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”

Clinical Context and Clinical Scenarios

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A.1 Purpose and Introduction

A.1.1 Purpose

The purpose of this Annex is to provide the clinical context for the development of standards for integrated medical device systems. The Clinical Scenarios [in Annex B of ASTM F2761-09] illustrate serious adverse events that could have been prevented through integrated medical systems, thus representing unmet safety and performance needs. The examples are representative, not exhaustive.

The Medical Device “Plug-and-Play” Interoperability program (www.mdnp.org) has identified high-level Clinical Scenarios from clinical publications, web sites, and interviews (“focus groups”) with clinicians and engineers. These scenarios have been expanded into “use cases” to aid in the development of appropriate integrated medical device system standards.

A.1.2 Methodology

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

Typical instructions and background for participants:

Assume that the integrated medical system provides seamless connectivity of medical devices to allow communication (e.g. remote data display, population of the electronic medical record, etc.) and integration of medical devices with control functions (e.g. control of infusion pumps from the anesthesia workstation, implementation of “safety interlocks” to stop an infusion at a pre-determined blood pressure value or to prevent intra-abdominal CO2 insufflation if the heart rate and blood pressure are unmonitored, etc.).

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

- a) Which clinical challenges exist today that could be solved by the proposed system?
- b) Which obstacles to safety, efficiency, and teamwork could be reduced or eliminated by the proposed system?

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- c) *How would this approach affect the practice environment, both clinically and from a business/process perspective?*
- d) *What risks can be introduced by an integrated medical system, and how could they be mitigated?*

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

A.1.3 Clinical Scenario

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

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

A.1.4 Clinical Concept of Operations (CConOps)

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

This description provides details of:

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

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