

These clinical scenarios 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”

The sections here have been numbered to match the standard.

Clinical Context and Clinical Scenarios

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B.2 Clinical Examples

B.2.1 Safety Interlocks

B.2.1.1 Clinical Scenario, Safety Interlock

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 Based on family wishes, life support was withdrawn and the patient died.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

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 SpO₂ (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, SpO₂ 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 SpO₂ 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 SpO₂ and respiration rate indicate distress, the system generates a “severe respiratory distress” high priority alarm condition sent via the distributed alarm system.

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Benefits of this new system:

- a) Sensitive and specific detection of respiratory compromise prior to irreversible injury;
- b) Discontinuation of medication infusion pump to slow or stop deterioration in respiratory status; and
- c) Provision of early, informative, notification to the clinical staff to enable early intervention.

Risks of this new system:

- d) inaccuracy of information in the physician’s orders;
- e) inaccuracy in the information systems;
- f) inaccuracy in clinical data which contribute to the algorithm; and
- g) unnecessarily stopping the infusion pump due to a false positive alarm condition for respiratory distress.

B.2.2 Synchronization with Safety Interlock

B.2.2.1 Clinical Scenario, Synchronization with Safety Interlock

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

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

B.2.2.2 CConOps, Synchronization with Safety Interlock

The patient is undergoing a surgical procedure under anesthesia and is connected to an anesthesia workstation, which is part of the integrated system. The radiology technician arrives in the operating room (OR) with a portable x-ray machine, which is connected to the integrated system and positioned to take an image. The phase of the breathing cycle in which the image is to be captured (inspiration or expiration) is entered into the system by the technician. The exposure time and x-ray activation latency of the

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

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

Benefits of this new system:

- a) Add error resistance to the x-ray procedure by eliminating the dependence on the operator (e.g. anesthesia provider) to remember to turn the ventilator back on;
- b) Shorten or eliminate the period of apnea, thereby reducing potentially adverse responses to apnea; and
- c) Provide the ability to synchronize x-ray exposure with inspiratory hold, without requiring anyone to be present in the x-ray exposure area to manually generate sustained inspiration.

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

B.2.3 Process Control (Workflow)

B.2.3.1 Clinical Scenario, Process Control

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

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

B.2.3.2 CConOps, Process Control

The patient is attached to a large volume infusion pump with heparin solution. During the setup of the large volume infusion pump, the dosage of the heparin IV bag is verified with the computerized provider order entry system. Heart rate, blood pressure, and respiration rate are measured. An IV line assessment is completed. When the integrated system recognizes that the medication being infused is heparin, it

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automatically places an order for serial PTT tests. Once the laboratory information system determines the PTT, the integrated system retrieves the results and an integrated system-hosted algorithm determines whether changes to the dosage need to be made, and the clinical staff is notified.

Benefits of this new system:

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

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

B.2.4 Smart Alarm System

B.2.4.1 Clinical Scenario, Smart Alarm System

Current State: Cardiac (heart) surgery typically requires the use of cardiopulmonary bypass (CPB). During CPB, the CPB machine takes over both the pumping function of the heart and the ventilation function of the lung. Therefore, during CPB, the anesthesia machine ventilator is usually not needed, and is turned off to prevent unnecessary ventilation-induced lung movement that can interfere with surgery. During this period, physiological respiratory and circulatory monitors can be turned off or their alarm signals inactivated to prevent nuisance alarm signals. At the conclusion of the CPB period, the heart resumes pumping blood, and the CPB machine pump is stopped. Lung ventilation must be resumed prior to discontinuation of CPB or non-oxygenated blood circulates and can cause organ damage. The anesthesia/surgical team has to remember to resume ventilation and manually re-start the anesthesia ventilator. Patient injuries and deaths occur when the team forgets or delays resumption of ventilation. This is a longstanding problem that continues to occur. [27] Immediately following CPB, the heart and other major organs can be especially susceptible to injury from poorly oxygenated blood.

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

B.2.4.2 CConOps, Smart Alarm System

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

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

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

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B.2.5 Decision Support

B.2.5.1 Clinical Scenario, Decision Support

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

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

B.2.5.2 CConOps, Decision Support

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

Upon arrival at the patient’s bedside, the integrated system presents the RRT with relevant current and historical physiological data, medication and allergy lists, and recent invasive procedures. The integrated system can present a differential diagnosis, cardiac arrest treatment algorithms, and support interventions with contextually relevant checklists.

Benefits of this new system:

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

Risks of this system:

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

B.2.6 Physiological Closed Loop Control (PCLC)

B.2.6.1 Clinical Scenario, PCLC

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

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

B.2.6.2 CConOps, PCLC

A patient is receiving IV insulin via a syringe pump, glucose solution via a large-volume infusion pump, and a large-volume infusion pump of saline is serving as the intravenous carrier solution. The patient is also attached to a continuous blood glucose monitor or an intermittent glucose monitor. At the time of connecting the patient to an IV infusion, the nursing staff completes assessments of vital signs and IV line integrity. Subsequently, the large volume infusion pump (saline carrier), syringe pump (insulin), and blood glucose monitor are attached to an integrated system that queries the patient record for weight, target glucose range, typical insulin dosage range (and correction factor), and glucose responsiveness to meals (insulin-to-carbohydrate ratio). The integrated system-hosted physiologic closed-loop control (PCLC) algorithm delivers IV insulin to maintain the blood glucose values within the clinically desired range. The clinical staff is alerted if the glucose level changes unexpectedly or outside the limits determined by the system. In order to maintain the glucose levels within the target range, the system can also change the glucose infusion rate utilizing an integrated system-hosted algorithm. The algorithm would alert the clinical staff if the glucose levels exceed a range that the algorithm can effectively manage by adjusting the insulin or glucose infusions.

Benefits of this new system:

- a) facilitate maintaining blood glucose concentration in a normal range;
- b) provide decision support to assist diabetes management; and
- c) prevent life-threatening hypoglycemic events.

Risks of this new system:

- d) Individual patients react to glucose differently and glucose management can be challenging; therefore the limits and values need to be specific to the patient; and
- e) Glucose levels rise and fall somewhat slowly and somewhat unpredictably, so these factors need to be considered by the system. (These issues are addressed more generally in IEC 60601-1-10.)

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

B.2.7.1 Clinical Scenario, MD PnP

Current State: A forty-one-year-old, 90 kg male underwent uneventful aortic valve replacement surgery and was transported to the ICU. His blood pressure (BP) was 130/70 mmHg and stable on arrival. He was placed on a lung ventilator following a routine ventilator pre-use system check. The ventilator settings were IMV = 8 breaths/min, tidal volume of 1 l, FiO₂ at 0.80, and zero positive-end expiratory pressure (PEEP). The ventilator was connected to the clinical information system so that device settings were observable at the central station and automated electronic health record documentation could be performed. Within 40 seconds of initiation of mechanical ventilation, acute hypotension developed (BP = 60/40 mmHg). Urgent evaluation by the surgical house staff focused on a presumed bleeding source or tension pneumothorax. Fortunately, evaluation by an experienced respiratory therapist and an intensivist noted the breathing system airway pressure was increasing with each breath, because the ventilator was not permitting full exhalation. The patient was immediately disconnected from the ventilator and lungs were manually ventilated with the transport ventilation system. Upon disconnection from the ventilator circuit, the patient’s chest visibly decreased in diameter, with an immediate improvement in blood pressure and peripheral perfusion. The expiratory valve of the ventilator was found to be defective. A replacement critical care ventilator – produced by a different manufacturer - was connected to the patient and mechanical ventilation resumed. [39]. The first ventilator was connected to the clinical information system, but the replacement ventilator was developed by a different manufacturer, so although it had the ability to connect to the central station, it required specialized cabling and data mapping. These connections could not be completed in real time by hospital technicians, so manual documentation of ventilation was required and remote electronic observation was unavailable.

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

B.2.7.2 CConOps, MD PnP

An ICU patient is in need of mechanical lung ventilation. A sanitized ventilator is obtained from hospital inventory. The routine pre-use safety check is performed. The biomed inspection sticker is reviewed for currency. The Plug-and-Play interface sticker is reviewed for currency. A sanitized device interface cable is obtained from ICU inventory and connected to the ventilator and to the patient headboard-mounted MD PnP data port. Following power-on self-test, the ventilator confirms connectivity to the clinical information system. (If loss of connectivity occurred, it is displayed by the ventilator.)

Benefits of this new system:

- a) ventilator data is readily available for electronic documentation, remote display, and distributed alarms to improve documentation quality and enhance clinical vigilance and diagnosis, and
- b) Standards-based connectivity permits all conformant ventilators in hospital inventory to be available for use in clinical settings where data connectivity is important to patient care.

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

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