

ALARM SYSTEM VOCABULARY

ALARM CONDITION

state of the alarm system when it has determined that a potential or actual hazardous situation exists for which operator notification is required

NOTE 1: An alarm condition can be invalid, i.e. a false positive alarm condition.

NOTE 2: An alarm condition can be missed, i.e. a false negative alarm condition.

[IEC 60601-1:2006+A1:2012, definition 3.1]

ALARM CONDITION DELAY

time from the occurrence of a triggering event either in the patient, for physiological alarm conditions, or in the equipment, for technical alarm conditions, to when the alarm system determines that an alarm condition exists

[IEC 60601-1:2006, definition 3.2]

ALARM LIMIT

threshold used by an alarm system to determine an alarm condition

[IEC 60601-1:2006, definition 3.3]

ALARM SETTINGS

alarm system configuration, including but not limited to:

- alarm limits;
- the characteristics of any alarm signal inactivation state; and
- the values of variables or parameters that determine the function of the alarm system

NOTE: Some algorithmically-determined alarm settings can require time to be determined or re-determined.

[IEC 60601-1:2006, definition 3.8]

ALARM SIGNAL

type of signal generated by the alarm system to indicate the presence (or occurrence) of an alarm condition

[IEC 60601-1:2006, definition 3.9]

ALARM SIGNAL GENERATION DELAY

time from the onset of an alarm condition to the generation of its alarm signal(s)

[IEC 60601-1:2006, definition 3.10]

ALARM SYSTEM

parts of medical electrical equipment or a medical electrical system that generate alarm conditions and, as appropriate, present alarm signals

[IEC 60601-1:2006+A1:2012, definition 3.11]

DEFAULT ALARM PRESET

alarm preset that can be activated by the alarm system without operator action

NOTE: manufacturer- or responsible organization-configured alarm presets are possible types of default alarm presets.

[IEC 60601-1:2006, definition 3.16]

DISTRIBUTED ALARM SYSTEM

alarm system that involves more than one item of equipment of a medical electrical system

NOTE: the parts of a distributed alarm system can be widely separated in distance.

[IEC 60601-1:2006, definition 3.17]

ESCALATION

process by which an alarm system increases the priority of an alarm condition or increases the sense of urgency of an alarm signal

[IEC 60601-1:2006, definition 3.18]

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FALSE NEGATIVE ALARM CONDITION

absence of an alarm condition when a valid triggering event has occurred in the patient, the equipment or the alarm system

NOTE: an alarm condition can be rejected or missed because of spurious information produced by the patient, the patient equipment interface, other equipment or the equipment itself.

[IEC 60601-1:2006, definition 3.20]

FALSE POSITIVE ALARM CONDITION

presence of an alarm condition when no valid triggering event has occurred in the patient, the equipment or the alarm system

NOTE: a false positive alarm condition can be caused by spurious information produced by the patient, the patient-equipment interface, other equipment or the alarm system itself.

[IEC 60601-1:2006, definition 3.21]

HIGH PRIORITY

indicating that immediate operator response is required

NOTE: the priority is assigned through risk analysis.

[IEC 60601-1:2006, definition 3.22]

INFORMATION SIGNAL

any signal that is not an alarm signal or a reminder signal

EXAMPLE 1 ECG waveform

EXAMPLE 2 SpO₂ tone

EXAMPLE 3 Fluoroscopy beam-on indication

[IEC 60601-1:2006, definition 3.23]

INTELLIGENT ALARM SYSTEM

alarm system that makes logical decisions based on monitored information without operator intervention

EXAMPLE 1 an alarm system that changes priority based on the rate of change of a monitored variable.

EXAMPLE 2 an alarm system that suppresses an alarm condition when a related alarm condition of higher priority has recently generated an alarm signal.

[IEC 60601-1:2006, definition 3.24]

LOW PRIORITY

indicating that operator awareness is required

NOTE: the priority is assigned through risk analysis.

[IEC 60601-1:2006, definition 3.27]

MEDIUM PRIORITY

indicating that prompt operator response is required

NOTE: the priority is assigned through risk analysis.

[IEC 60601-1:2006, definition 3.28]

OPERATOR

person handling the equipment

[IEC 60601-1:2005, definition 3.73]

PATIENT

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

NOTE: A patient can be an operator.

[IEC 60601-1:2005+A1:2012, definition 3.76]

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PHYSIOLOGICAL ALARM CONDITION

alarm condition arising from a monitored patient-related variable

EXAMPLE 1 High exhaled anesthetic agent concentration.

EXAMPLE 2 Low exhaled tidal volume.

EXAMPLE 3 Low oxygen saturation measured by pulse oximetry.

EXAMPLE 4 High arterial pressure.

EXAMPLE 5 High heart rate.

[IEC 60601-1-8:2006, definition 3.31]

RESPONSIBLE ORGANIZATION

entity accountable for the use and maintenance of an medical electrical equipment or an medical electrical system

NOTE 1: The accountable entity can be, for example, a hospital, an individual clinician or a layperson. For in home use applications, the patient, operator and responsible organization can be one and the same person.

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

[IEC 60601-1:2005, definition 3.101]

RISK

combination of the probability of occurrence of harm and the severity of that harm

[IEC 60601-1:2005, definition 3.102]

RISK ANALYSIS

systematic use of available information to identify hazards and to estimate risk

[IEC 60601-1:2005, definition 3.103]

RISK ASSESSMENT

overall process comprising a risk analysis and a risk evaluation

[IEC 60601-1:2005, definition 3.104]

RISK MANAGEMENT

systematic application of management policies, procedures and practices to the tasks of analyzing, evaluating and controlling risk

[IEC 60601-1:2005, definition 3.107]

TECHNICAL ALARM CONDITION

alarm condition arising from a monitored equipment-related or alarm system-related variable

EXAMPLE 1 An electrical, mechanical or other failure.

EXAMPLE 2 A failure of a sensor or component (unsafe voltage, high impedance, signal impedance, artifact, noisy signal, disconnection, calibration error, tubing obstruction, etc.).

EXAMPLE 3 An algorithm that cannot classify or resolve the available data.

[IEC 60601-1-8:2006, definition 3.36]