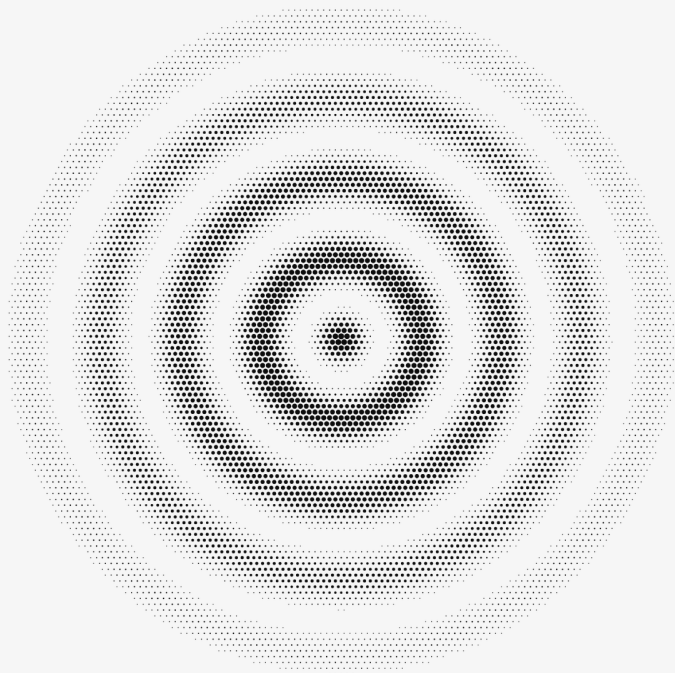




GUIDE 10 ALARM SYSTEMS

Why the alarm did not help

How a medical alarm system is designed under IEC 60601-1-8, the settings and states that decide whether anyone hears it, and how to reconstruct what the alarm did.



ABOUT

In many device events the device knew. It detected the condition, raised an alarm, and recorded that it did. The question is what happened between the detection and the response, and that question has a structure.

This guide explains how alarm systems are designed and classified, the chain from a condition to a human response and where each link can fail, the settings that decide what the alarm does, and the records that show what it did on the day.

FOR

Legal counsel who must establish whether an alarm sounded, who could have heard it, and why it was set the way it was.

Manufacturers — systems, software, and usability engineers who assign priorities and design alarm behaviour.

Hospitals — nursing leadership, clinical engineering, and risk management who set alarm policy and configure devices.

NOTE

This guide is general technical information. It is not legal advice. Terms follow IEC 60601-1-8 (the collateral standard for alarm systems in medical electrical equipment) and its amendments; device-specific behaviour is defined in each manufacturer's documentation.

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01

What an alarm system is

The standard defines an alarm system as the parts of a device that detect alarm conditions and generate alarm signals. The vocabulary matters, because the records use it and the design decisions are made in it.

CONDITION	A state in which the alarm system has determined that a potential or actual hazardous situation exists and operator awareness or response is required. Physiological (a measured value outside limits) or technical (a sensor off, a battery low, an occlusion).
PRIORITY	High, medium, or low, assigned by the manufacturer from the harm that could follow if no one responds and how fast that harm arrives. The assignment is a risk management decision and must be recorded.
SIGNALS	Auditory and visual signals whose pattern, colour, and flash rate are set by priority so that the same priority sounds and looks the same across devices. Red flashing for high, yellow flashing for medium, yellow or cyan steady for low.
STATES	Audio paused, audio off, alarm paused, alarm off, and acknowledged. Each state suppresses something for a time or until reset, and each must be indicated. The state at the moment of the event is often the whole question.
LIMITS	The values that define a physiological alarm condition. Set per patient, or taken from a default preset the manufacturer ships and the facility may change.

NOTE

A device may detect a condition and generate no signal, because of a state or a delay the designer allowed. “The alarm went off” and “the alarm condition existed” are different facts, and the log records them separately (guide 07).

FIGURE

How priority is assigned

The standard gives a matrix. The manufacturer places each alarm condition in it by the potential result of a failure to respond and by the onset of that harm, and the cell gives the priority. A placement that differs from the matrix needs a written reason.

	Immediate onset	Prompt onset	Delayed onset
Death or irreversible injury	High	High	Medium
Reversible injury	High	Medium	Low
Minor injury or discomfort	Medium	Low	Low or no alarm

High priority
Immediate response. Red, flashing fast. Ten-pulse auditory burst, repeated.

Medium priority
Prompt response. Yellow, flashing slowly. Three-pulse burst, repeated.

Low priority
Awareness. Yellow or cyan, steady. One or two pulses, or none.

FIG 01 Onset is the time from the condition to the harm: immediate within a time not usually enough for manual corrective action, prompt within a time enough for it, delayed otherwise. The manufacturer's estimate of onset for each condition is in the risk file (guide 04).

02

From condition to response

An alarm is a chain of six links. An event is reconstructed by asking which link held and which did not.

01

Detection

The sensor measured, the algorithm compared, and the condition was declared. A sensor off the patient, a filter, or an artefact rejection rule can delay or prevent this. The trend log shows the value; the alarm log shows the declaration.

02

Delay

A condition delay before the condition is declared, and a signal generation delay before the signal starts. Both are design choices, set to reduce nuisance alarms; both are specified in the documentation and must be justified in the risk file against the onset of harm.

03

Local signal

Sound and light at the device, at the set volume and priority. Suppressed by an audio pause, an audio off state, or a volume set to the minimum the device allows.

04

Distribution

A central station, a pager, a phone, or a nurse-call relay. A distributed alarm system has its own delays, its own confirmation rules, and its own failure modes, and the standard treats it as part of the alarm system when it is relied upon.

05

Perception

Someone within range of a signal, able to distinguish it from the others sounding, and not habituated to it. Alarm load on the unit is a fact of the environment and a design input.

06

Response

The time from perception to action, against the onset of harm. The clinical record and the device log together show it.

03

The settings that decide

Most of what an alarm system does on a given day was decided earlier, by a configuration. The settings below are the ones that most often explain an event. Each has a default from the manufacturer and a current value that someone set.

LIMITS

Wide limits suppress alarms; narrow limits multiply them. The default preset, the facility's standard configuration, and the per-patient settings are three different records.

PAUSE

How long an audio pause or an alarm pause lasts, whether it can be repeated, and whether the device returns to alarming on its own. Some devices allow an audio-off state with no time limit; the standard requires it to be indicated.

VOLUME

The minimum volume the device permits, whether audio off is permitted at all, and what the device shows when it is. A device configured with audio off and relying on a central station has moved the chain to the network.

LATCHING

Whether a signal continues after the condition has ended until acknowledged. A non-latching signal for a short-lived condition may have sounded and stopped before anyone looked.

ESCALATION

Whether a condition that persists raises its priority or its volume, and after how long. A medium-priority condition left for an hour is a design question.

KEY POINT

The configuration in force at the time is a record. If the device does not keep the history of changes, the facility's policy, the service records, and testimony have to supply it.

04 What to request

From the manufacturer, under the record map in guide 05, and from the facility. The device's own log is the subject of guide 07.

01 Alarm specification

Every alarm condition the device can declare, its priority, the rationale for the priority, the condition and signal delays, and the default limits and presets.

02 Risk file entries

The hazards each alarm condition addresses, the estimated onset of harm, and the verification that the alarm is an effective control (guide 04).

03 Standard test report

The IEC 60601-1-8 test report for the version: which clauses were tested, how, and the results, including signal characteristics and the behaviour of each state.

04 Usability file

The evaluation of the alarm system with representative users under IEC 62366-1: whether the states, the pauses, and the priorities were understood in use (guide 12).

05 Distributed system records

The specification and validation of the central station or messaging link, its delays and fallbacks, and its logs for the period.

06 Facility records

The alarm management policy, the standard configuration for the unit, the per-patient settings, the central-station logs, and the alarm counts for the unit in the period.

05 Reading the event

With the records in hand, the chain is walked once, in order.

01 Was the condition declared?

The alarm log entry, its time, and the trend values before it. If no entry, the trend shows whether the value crossed the limit, and the specification shows what delay or rule applied.

02 What priority and what signal?

The priority from the specification, the signal it should have produced, and the volume setting in force.

03 What state was the system in?

Audio paused, audio off, alarm paused, acknowledged: from the log, with the time the state began and who set it where the device records it.

04 Where did the signal go?

The local signal; the central station; any message sent, delivered, and acknowledged, each with a time from its own log.

05 Who could have perceived it?

Staffing and location from the facility's records; the alarm load on the unit in the hour from the central station; the volume and the environment.

06 What was the response?

The clinical record against the device log, on one timeline (guide 15), with the onset of harm from the risk file beside it.

06 Where the record is weak

These are the findings an engineering reviewer looks for first in an alarm event.

01 **A priority below the matrix**
The condition sits in a cell that gives high; the device assigns medium or low, and the rationale is missing or rests on nuisance-alarm reduction alone.

02 **A delay longer than the onset**
The condition delay plus the signal delay exceeds the time to harm the risk file itself estimates.

03 **Audio off without a clear indication**
The device permits audio off, and the state is shown by a small icon that the usability file never tested.

04 **Defaults set wide**
The manufacturer's preset, or the facility's standard configuration, puts the limit beyond the range the condition is meant to catch.

05

A pause with no return

An alarm pause that does not end on its own, or can be repeated without limit, with no escalation.

06

A distributed system that was never validated

The central station or messaging link was relied upon, and no record shows its delays, its fallbacks, or its performance that day.

07

A log that does not record state

The alarm log shows conditions but not pauses, audio-off states, or volume; the state at the moment has to be inferred.

NOTE

An alarm that sounded and was not answered, and an alarm that could not be heard, are different events with different records. The chain shows which it was.

CHECKLIST

Alarm systems at a glance

- ☐ Alarm specification obtained: conditions, priorities, rationale, delays, defaults
- ☐ Risk file entries for the conditions, with estimated onset of harm
- ☐ IEC 60601-1-8 test report for the version, with the clauses run
- ☐ Usability evaluation of the alarm system obtained
- ☐ Distributed alarm system specification, validation, and logs for the period
- ☐ Facility alarm policy, unit configuration, and per-patient settings
- ☐ Central-station logs and alarm counts for the unit and the hour
- ☐ Device alarm log, trends, settings history, and state changes, with clock reference
- ☐ Chain walked: detection, delay, local signal, distribution, perception, response
- ☐ Priority placed in the matrix and compared with the assignment
- ☐ Settings in force compared with defaults and with policy
- ☐ Event placed on the timeline with the onset of harm beside it (guide 15)

SOURCES

Sources and further reading

IEC 60601-1-8 — Medical electrical equipment: general requirements, tests and guidance for alarm systems (with amendments 1 and 2)

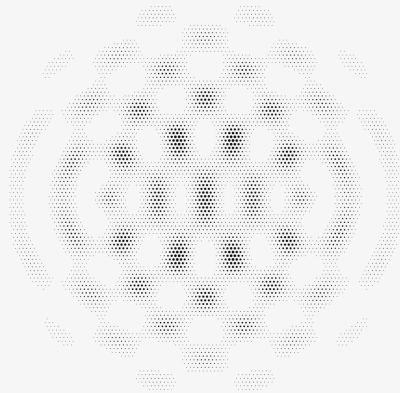
iec.ch

The Joint Commission — National Patient Safety Goal
NPSG.06.01.01, clinical alarm safety

jointcommission.org

ISO 14971:2019 and IEC 62366-1 — risk management and usability engineering, as applied to alarm conditions and alarm states

iso.org



SERVICES

We reconstruct the alarm chain, link by link

We read the alarm specification and the risk file as the engineers who wrote them, decode the device log, and measure on the bench what the device does in each state and at each setting.

01

The specification and the matrix

Every alarm condition placed in the priority matrix, with the manufacturer's rationale, delays, and defaults beside it.

02

The log and the chain

Alarm, trend, and state entries aligned to the clinical record; the six links walked and each one documented.

03

Bench measurement

Signal level, pattern, and timing measured on an exemplar in the configuration in force, including the paused and audio-off states.

TERMS

Terms used in this guide

Alarm system

The parts of a device that detect alarm conditions and generate alarm signals.

Alarm condition

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

Alarm signal

The sound, light, or message the alarm system produces for an alarm condition.

Priority

High, medium, or low: the urgency of the response required, assigned by the manufacturer from the potential harm and its onset.

Alarm limit

The threshold that defines a physiological alarm condition, set per patient or from a default preset.

Audio paused, audio off

States in which the auditory signal is suppressed for a time, or until reset, while the condition may continue.

Latching

An alarm signal that continues after the alarm condition has ended, until the operator acknowledges it.

Distributed alarm system

A system that sends alarm conditions to another place: a central station, a pager, a phone. Part of the alarm system when it is relied upon.

Tell us about the device.

Send a short description of the device, the event, and any deadlines. We will tell you what to preserve now and recommend the next steps.

EMAIL info@alphadevices.io

WEB alphadevices.io

GUIDES

- | | | | |
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