Patient monitoring alarms in the ICU and in the operating room

Felix Schmid*, Matthias S Goepfert, Daniel A Reuter

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Introduction
Historically, the word ‘alarm’ originates from the Latin, ‘ad arma’, or the French, ‘à l’arme’, which can be translated into ‘to your weapons.’ Hence, the word indicates a call for immediate action, for attack or for defense. Alarms have existed ever since humans have lived in groups. Some of the first documented alarms are watchmen on towers in the Middle Ages, who warned of fires or enemies by ringing bells. Warning fires provided a visual alert to enemy attacks, visible across long ranges and enabling an early reaction of armed forces. Today, comparable systems are available that send warning-SMSs (Short Message Service) of nearing tsunamis to mobile phones [1].

In complex fields of work like aviation, mining, anesthesiology, and intensive care medicine — and here particularly with regard to monitoring of vital functions — alarms are ubiquitous and have been the subject of medical, technical, and psychological research for decades [2,3]. Monitoring of vital functions and function of life-support devices is essential for critically ill patients, although real evidence based data are missing. However, modern patient monitors and implemented risk management (including alarms) must be constructed in accordance to approved and current international standards IEC 60601-1-11 and IEC 80001-1 [4,5]. Tinker et al. surveyed 1,175 anesthetic-related closed malpractice claims from 17 professional liability insurance companies. It was determined that 31.5 % of the negative outcomes could have been prevented by use of additional monitors. The authors concluded that monitoring with adequate thresholds appeared able to improve patient outcomes [6]. Cooper et al. showed in the 1980s that 70 % of all anesthesia-related critical incidents were caused by human error [7]. Similar data are available from the aviation industry [8]. Inevitable mistakes may be corrected in time if detected by a monitoring system (including alarms) before physiological variables run out of range.

An alarm is an automatic warning that results from a measurement, or any other acquisition of descriptors of a state, and indicates a relevant deviation from a normal state [9]. Loeb surveyed the reaction of anesthesiologists to relevant changes in monitoring parameters, and showed that anesthesiologists needed a mean time of 61 seconds to recognize a change in the parameters; 16 % of the changes were unrecognized for over 5 minutes [10]. In contrast, Morris and Montano studied the reaction of anesthesiologists to optical and acoustic warnings during maintenance of general anesthesia. The anesthesiologists showed a reaction time of 6 seconds to optical warnings and 1 second to acoustic warnings [11]. An ideal alarm should only detect immediate or threatening danger that requires prompt attention. The alarm design should adequately represent the underlying situation. The announcement of the alarm should be instantly perceptible in critical situations. Additionally, the user should be informed of circumstances that impair the reliability of the alarming system.

In addition to these general properties, device alarms have various goals, which follow a certain hierarchy [12]:

- Detection of life-threatening situations: The detection of life-threatening situations was the original purpose of monitor alarms. False negative alarms are not acceptable in such situations because of the danger of severe patient harm or death.
- Detection of imminent danger: The early detection of gradual change that might indicate imminent danger.
- Diagnostic alarms: These alarms indicate a pathophysiological condition (e.g., shock) rather than warning of ‘out-of-range’ variables.
- Detection of life-threatening device malfunction: This ability is essential for all life-support devices, which
must recognize malfunctions, such as disconnection from the patient, occlusion of the connection to the patient, disconnection from power, gas, or water supply, and internal malfunction.

- Detection of imminent device malfunction: The early detection of device-related problems that could result in malfunction is an integral part of many therapeutic devices. These warning mechanisms range from simple aspects (e.g., low-battery warnings) to complex algorithms and sensors that track the wear of respiratory valves.

Alarm design
Alarms are typically displayed in two ways or as a combination of both:

1. Acoustic
   The alarm is given as a warning sound. Most manufacturers distinguish the priority of an alarm with different signals. Intuitive alarms with different tone sequences (e.g., ‘short-long-short’ for ‘ven-ti-late’) have been the object of research but have not found their way into routine clinical practice. Alarms directly mentioning organ systems, device hardware, or parts of it (e.g., ventilation or circulation) or alarms with direct labeling of the physiological problem (‘blood-pressure’ or ‘oxygen’) have also not been introduced into practice [13].

2. Visual
   Visual alarms involve mostly flashing or coloring of the related parameter in an eye-catching manner. Some systems provide integrated displays of several parameters. One example is a spider-display, which shows the relationship of different parameters in a stylized spider web. Such applications can be useful to display different parameters in context. Compared to other professions in industry and aviation, adoption of such new displays in healthcare has been slow.

Alarm-related problems
Alarms help to prevent patient harm by providing rapid recognition of and reaction to critical situations, but only if they are not ‘false alarms.’ Medical progress leads to an increasing number of ‘monitorable’ parameters and thus an increasing number of possible alarms.

False alarms
In medicine, false alarms are conventionally defined as alarms without clinical or therapeutic consequence. Today’s monitoring systems are still designed using a ‘better-safe-than-sorry’-logic: A large number of false alarms are accepted rather than risking missing one valid alarm [14]. Alarms can be differentiated into technically correct/technically false and clinically relevant/clinically not relevant. Alarms can be classified as technically correct, if they are based upon a technically correct measurement. Technically false alarms are not based on a technically correct measurement (e.g., interference with pulse oximetry caused by ambient light). Because not all technically correct alarms are clinically relevant, they can be further differentiated into clinically relevant or not relevant (e.g., inadequate thresholds).

False alarm rates
There are several studies in the medical literature about monitoring alarms in anesthesiology and intensive care medicine. Lawless suggested that 94% of all alarms in a pediatric intensive care unit (PICU) were clinically irrelevant [15]. Tsien and Fackler also found that 92% of alarms were false alarms in their observation in a PICU [16]. In both studies, all alarms were recorded by the nursing staff, who also assessed their relevance and validity. O’Carroll reported that only 8 of 1,455 alarms were caused by potentially life-threatening situations [17]. An observation by Siebig and co-workers showed that these results are not limited to the PICU. These authors digitally recorded all the alarms for 38 patients on a 12-bed medical ICU and retrospectively assessed their relevance and validity: Only 17% of the alarms were relevant, with 44% being technically false [18]. Chambrin et al. conducted a multicenter study in 1999, including 131 medical ICU patients. The medical staff recorded all alarms, which were assessed according to their relevance and the reaction of the medical staff. Twenty-six percent of the alarms had marginal consequences, for example leading to re-positioning of sensors. In only 6% did the alarm lead to a call for a doctor. Seventeen percent were the result of technical problems and 24% were caused by staff manipulation [14].

In contrast to ICU observations, there are only a few studies about false alarms in perioperative settings. Comparison between the ICU and the operating room (OR) is limited in part because ICU patients are only sedated and not anesthetized, causing higher rates of patient movement artifacts. Furthermore, in the OR, changes in patients’ conditions often occur much more rapidly than in the ICU because of changes in the depth of anesthesia and surgical manipulation (e.g., extensive blood loss).

Schmid et al. [19] studied perioperative alarms in a highly complex surgical setting and included 25 patients undergoing elective cardiac surgery with extracorporeal circulation. All patient monitor and anesthesia workstation alarms were digitally recorded. Additionally, the anesthesiology workplace was videotaped from two angles to allow better assessment of external influences, retrospectively. During 124 hours of monitoring, 8,975 alarms were recorded: 7,556 alarms were hemodynamic alarms, 1,419 alarms were ventilation-related. This
corresponded to 359 ± 158 alarms per procedure (1.2 alarms/minute). The reaction time to the alarms was on average 4 seconds. Of all the alarms, 96 % were caused by threshold violations. Of the 8,975 alarms, 6,386 were classified as serious and life-threatening and analyzed by threshold violations. Of the 8,975 alarms, 6,386 were classified as relevant, 2,703 (61 %) were not relevant.

These results supported earlier studies in less complex settings. Seagull and Sanderson surveyed perioperative alarms in different surgical disciplines (arthroscopic, cardiac surgery, abdominal surgery, and neurosurgery) with 6 cases in each discipline. The authors found 72 % of alarms had no clinical consequences [20]. A study by Kestin et al. [21] included 50 pediatric patients (1 month to 10 years old) in the OR of a pediatric hospital (pediatric surgery, eye surgery, dental surgery, orthopedic surgery) and also found that 75 % alarms had no therapeutic consequences (1 alarm per 4.5 minutes on average). Only 3 % of all alarms indicated critical situations [21]. However, the studies by Kestin [21] and Seagull [20] were limited by the fact that 5 and 6 different monitors, respectively, were used in these observational studies.

Artifacts: a common source of false alarm
Many false alarms are caused by artifacts. The main sources of artifact are well known and are of physiological and non-physiological origin. Most of these artifacts directly influence the measured signals [22], leading to incorrect measurements and this, in turn, triggers the alarm. The most common artifacts and their sources are listed in Table 1.

Consequences of false alarms
The story of “the shepherd who cried wolf” appears in Aesop’s Fables and, with some minor variations, can be found in the folklore of many different cultures. “One day, just to stir up excitement, the shepherd boy rushed down from the pasture, crying ‘Wolf! Wolf!’ The villagers heard the alarm and came running to help chase the marauder away, only to find the sheep peaceful and no wolf in sight. But there came a day when a wolf really came. The boy screamed and called for help. But all in vain! The neighbors, supposing him to be up to his old tricks, paid no heed to his cries, and the wolf devoured the sheep!” [23].

Based on this Fable, Breznitz formed the phrase “Crying-Wolf-Phenomenon” for the desensitization caused by high false alarm rates, with the possible consequence of ignoring relevant alarms [24]. The high incidence of false alarms in anesthesiology and intensive care medicine is not only a disturbance but a risk factor when relevant alarms in critical situations are ignored. That this phenomenon is not limited to monitoring alarms was impressively demonstrated by the attack of the Japanese air force on the United States Navy at Pearl Harbor, Hawaii on December 7, 1941. Despite a valid advance warning by the new radar technology, no appropriate reaction followed. The simultaneous report of a contact and the destruction of an enemy submarine also did not lead to a reaction because the commanding admiral wanted to wait for confirmation due to frequent false alarms [25].

Various studies have shown that anesthesiologists’ reaction times to alarms increases in situations where there is low alarm validity [26,27]. The annoyance from false alarms may also lead to complete inactivation of alarms or to inappropriately wide threshold settings by the clinical user to limit alarms as much as possible. Thereby, the ‘mesh of the alarm-net’ gets wider and the risk of missed relevant alarm increases [28].

Medical staff and alarms
Alarms in the ICU and in the OR frequently lead to sound levels up to 70 dB(A). This level corresponds to heavy traffic. Sound levels up to 90 dB are not rare [29]. In a study by Hagerman et al., 94 patients with chest pain were retrospectively distributed into a good and poor acoustic group. Acoustics were altered during the study period by changing the ceiling tiles throughout the ICU from sound-reflecting (poor acoustics) to sound-absorbing tiles (good acoustics) of similar appearance. The patients were asked to complete a questionnaire about the quality of care. The patients considered the staff attitude was much better in the good acoustics period [30]. Increased sound levels caused by alarms can impact on the health of the medical personnel. In 1988, Topf and Dillon demonstrated the relationship between increased sound levels in ICUs and burn-out syndromes in ICU nurses [31].

Patients and alarms
For undisturbed night-sleep, sound levels below 40 dB(A) are recommended. As sound levels on the ICU are frequently above this level, sleep deprivation in ICU patients is well recognized [32]. Sleep deprivation in ICU patients leads to an impairment of the immune response and increased sympathetic nervous system activity: Catecholamine secretion increases heart rate, metabolism, and oxygen consumption [33]. Frequent arousal from sleep may lead to cardiac arrhythmias in patients with pre-existing heart disease but also in healthy patients [34]. Minckley reported significantly increased opioid needs when noise levels were high in her observation of 644 postoperative patients [35]. In the study by Hagerman et al., patients during the good acoustic (sound-absorbing ceiling tiles) period had lower pulse
amplitude values than those in the bad acoustic group; patients in the bad acoustics group also had higher rates of re-hospitalization after 1 (18% vs. 10%) and 3 months (48% vs. 21%) [30]. In a recent study, Van Rompaey et al. found reduced rates and later onset of delirium in patients who slept with earplugs at night [36].

Technical approaches for false alarm reduction
Essentially, there are three technical approaches to help reduce false alarms: (1) improving signal extraction (prevention or detection of artifacts); (2) improving algorithms for alarm generation; (3) improving alarm validation. An algorithm for alarm generation can be based on a single parameter (e.g., heart-rate or mean arterial pressure) or on several parameters simultaneously (e.g., heart rate detection from electrocardiogram [EKG], pulse oximetry oxygen saturation [SpO₂] and arterial line). Most devices are equipped with alarms based on a single parameter. In recent years, different approaches for false alarm reduction have been developed.

Phase specific settings
Observations, especially in surgical settings, have shown that different phases of the surgical procedure are characterized by different numbers and types of false alarms and also different patterns of alarms and specific reactions by the medical staff (e.g., during induction and emergence of anesthesia, during extracorporeal circulation, or single lung ventilation, or suctioning of patients). Schmid et al. found different characteristic patterns and density of alarms in 4 different intraoperative phases (beginning of surgery, start of extracorporeal circulation [ECC], end of ECC, end of surgery) [19]. Seagull and Sanderson also differentiated three different phases in anesthesia procedures (introduction, maintenance and emergence) and found characteristic patterns of alarms and alarm reactions in each phase [20]. This knowledge could be used for the development of phase specific settings to reduce false alarms (e.g., for specific settings for surgery or on the ICU).

Integrated validation of alarms (cross checking)
Matching of different parameters can be used for the reduction of false alarms: e.g., a ‘ventricular fibrillation’ alarm can be assumed to be false in the presence of undisturbed pulse oximetry and arterial blood pressure waveforms. Aboukhalil et al. [37] were able to reduce the incidence of false arrhythmia-related alarms from 42.7%
to 17.2 % in an offline application on a database of 447 patients (5,386 arrhythmia alarms). However, 9.7 % of the true cases of ventricular fibrillation were not detected; this situation is inadmissible for a lethal arrhythmia. Removal of ventricular arrhythmias from the algorithm still resulted in reduction in the incidence of false alarms to 22.7 % [37].

Implementation of time delays
Görges et al. [38] showed in an ICU setting and Schmid et al. [19] in an intraoperative setting that a great number of false alarms are caused by only mild threshold violations of short duration. In an offline validation, Görges et al. showed that the implementation of a 14-second delay reduced false alarms by 50 %; a 19-second delay reduced false alarms by 67 %. However, a simple delay carries the risk of unrecognized critical situations of short duration (e.g., short self-limiting tachycardia). The implementation of a graduated delay brings additional safety and flexibility to that approach. First, severe deviations are alarmed faster; this results in improved patient safety. Second, the graduation offers the possibility of a prolonged delay (more than 14 seconds) in cases of only moderate and clinically not-relevant deviations. However, studies using such an approach are still missing.

Statistical approaches for false alarm reduction
Improved signal extraction is an essential approach for reduction of false alarms caused by artifacts. Several approaches have been developed over the last decades.

Autoregressive models and self-adjusting thresholds
An autoregressive model describes measurement values as a linear transformation and integrates previous values plus a random error. An autoregressive model is appropriate for the observation of values in steady-state and for alarm generation caused by deviation from steady-state. It is also used for generation of self-adjusting thresholds, because of integration of the individual patient’s condition. However, self-adjusting thresholds always have to be elaborated and confirmed by the user [9].

Statistical process control
Statistical approaches are commonly used in alarm systems to detect ‘out-of-control’ states in a process. The original applications were in industrial production processes but they are also used for alarm generation. Kennedy used a process control approach to detect the onset of changes in systolic blood pressure [39]. The algorithm was tested on an existing database and detected 94 % of changes correctly, whereas anesthesiologists only detected 85 %.

Median filters
The median filter is a non-linear, signal processing method used for removal of short-term noise in measurement signals without influencing the baseline signal. For this purpose, the median is calculated for a defined interval. Thus, the signal is ‘smoothed’ and short noises, such as movement artifacts or interference from electrosurgery, are eliminated. This method is limited in long-lasting interferences that exceed the adjusted duration of the filter. Mäkivirta et al. [40] evaluated the effectiveness of a combination of a “short” (15 seconds) and a “long” (2.5 minutes) filter in a database of 10 cardiac surgery patients. The use of the filter increased the alarms that had therapeutic consequences from 12 to 49 %; the authors declared that no relevant alarms were missed.

Artificial intelligence
Although statistical approaches are predominantly used for the reduction of artifacts, artificial intelligence offers the possibility of integrating more complex contexts. This approach tries to validate alarms by imitating human thinking. Artificial intelligence can be embedded into decision-making systems. A paper by Imhoff and Kuhls provides an overview of artificial intelligence use in intensive care monitoring [9].

Rule-based expert systems
Rule-based expert systems are based on an integrated expert knowledge database. Some early rule-based expert systems were developed for medical use in the 1970s (MYCIN-System, ONCOCIN-System) [41]. These early systems applied expert knowledge from a database into a new context and simulated expert decisions in oncology and therapy of infectious diseases. In 1993, Sukuvaara et al. [42] developed an alarm system for the detection of hypovolemia, hyperdynamic circulation, left-heart failure, and hypoventilation. Although results showed that rule-based expert systems work well in the context of pathologic conditions, they have not been introduced into the clinical arena. The expansion of rule-based expert systems by so-called machine-learning is possible, whereby the pre-existing database is updated by actual patient data.

Neural networks
Neural networks were developed to imitate the neuronal process of human thinking. They are able to anticipate the presence of diseases on the basis of advance information (e.g., hemodynamic data from a myocardial infarction study group). Baxt and Skora [43] developed a neural network for early detection of myocardial infarction in patients admitted to a hospital with chest pain. The system was “trained” to detect specific changes in patients with myocardial infarction by implementation of a database (350 patients, 120 of whom had myocardial
infarction). The results showed that the neural network was able to detect or to exclude infarction with a sensitivity and specificity of 96%. The doctors at the respective emergency department achieved an average sensitivity of 73.3% and specificity of 81.1%. Neural networks have also been used for alarm generation in anesthesia ventilators [44].

Fuzzy logic
Fuzzy logic was introduced by Zadeh in the 1960s [45]. A common problem in clinical routine is the aim for objectivity and precision when the information does not allow an explicit conclusion. Fuzzy logic allows diffuse processing of exact data. Fuzzy logic is widely used in industry (e.g., for picture stabilization in cameras). Goldman and Cordova [46] demonstrated a patient monitor that was able to diagnose a simulated cardiac arrest by evaluation of EKG, capnography, and arterial blood pressure using fuzzy logic.

Bayesian networks
Bayesian networks have been used for estimation of event occurrence. In patient monitoring, they can be used for decision support. Laursen developed software for cardiac event detection [47]. The software continuously compared different physiologic parameters and their changes; thus, it was possible to check values against each other for plausibility and to anticipate cardiac events.

Conclusion
Medical progress has led to obvious improvements in ICU and perioperative monitoring over recent decades. With the increase in ‘monitorable’ parameters, rates of alarms have also increased. But technical progress has rarely affected the rates of false alarms. In addition to noise-related increase in burn-out rates, false alarms lead to desensitization of medical staff to alarms with the risk of critical situations potentially being ignored despite correct alarming. Patients are also directly affected by alarm-related sleep disorders with subsequent development of delirium and increased sympathetic nervous system activity and catecholamine secretion. In recent years, many promising approaches using statistical methods and artificial intelligence have been developed for the reduction of false alarms without obvious changes in false alarm rates in our clinical reality.

Competing interests
The authors declare that they have no competing interests.

List of abbreviations used
- ECC: extracorporeal circulation; EKG: electrocardiogram; EMG: electromyogram; ICU: intensive care unit; MRI: magnetic resonance imaging; PICU: pediatric intensive care unit; \( \text{SpO}_2 \): pulse oximetry oxygen saturation.

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