Bernoulli Smart Alarms & Surveillance: Applying Analytics in Real-Time

Introduction

Patient care devices (PCDs) produce alarms base on pre-defined thresholds that are established as defaults within the individual medical devices equipment. These machine-issued alarms are normally set to a standard default based on the practice of medicine defined by published guidelines and protocols, and are further refined or customized based upon an individual hospital's best practices, learnings, policies, studies and clinical preferences of medical staff.

Yet, individual alarms issued by standalone PCDs are independent of one another and produce alarms based on their localized measurements. Furthermore, individuation of the alarm thresholds, if desired by clinicians to provide tailored alarm settings per patient, can be unmanageable logistically. For instance, if it were desired to employ customized thresholds in a standard intensive care unit with 20 rooms, each room equipped with a physiologic monitor, the thresholds on each individual monitor would need to be set for each patient based on the care provider's orders. This would entail visiting each monitor and manually adjusting the individual thresholds. Making such changes can introduce error in configuration, particularly if the clinical staff are unaware of how to make such changes. Furthermore, when patients are discharged and new patients are brought in, the need to return the monitor to original default settings must be remembered or else settings from a prior patient will exist on the monitors and these settings may not be appropriate for the new patients. Making such changes is a non-trivial logistical undertaking that can induce patient safety hazards due to forgetfulness and distracted staff attentions.

To counteract the hazards and workflow impacts of these scenarios, a centralized surveillance platform is necessitated whereupon individual alarms can be set on a per-patient basis, viewed, escalated and acknowledged. But, the mere acknowledgement and viewing of alarms is insufficient: there must be a mechanism for creating and setting alarms that are separate from the patient care devices but that will not interfere with the settings on any one particular medical device. Rather, default settings of the individual patient care devices at the bedside can remain at some homogeneous standard levels and the settings can be managed on a clinical surveillance platform (Bernoulli One™) individually or in groups. Better yet, in order to quiet the environment around the patient, alarm settings on the individual devices supporting any one patient can be widened and tighter monitoring can be managed using the surveillance platform.

Research and independent findings suggest that improved surveillance and increased patient safety can be achieved through the use of continuous monitoring. Furthermore, the identification of hypoventilation, CO2 narcosis and apnea are most effectively accomplished via continuous monitoring of respirations and end-tidal carbon dioxide through capnography together with pulse, pulse oximetry and blood pressure. Changes in single parameter values may not be a good indicator of patient respiratory compromise. Hence, monitoring of multiple parameters to assess their interrelationships is an important capability that Bernoulli brings through the Bernoulli One platform, as multiple independent measurements can be correlated and associated with user-defined clinically-significant criteria that, when evaluated together, can yield important early indicators of pending compromise. [1] [2] [3] [4] [5] [6]

Limit alarms are, perhaps, the most direct and simplistic of alarm signals. Limit alarms annunciate when a particular measurement from a specific parameter exceeds a known threshold on that parameter. For example, when a heart rate measurement exceeds a tachycardia threshold of, say, 130 beats per minute, or when a respiration measurement falls below a lower limit of 6 breaths per minute. Patient care devices can individually provide for default settings in terms of limit thresholds on parameters, and are the norm for all physiologic monitor, mechanical ventilator, and most ad-hoc measurement devices used around the patient. The challenge occurs when limit thresholds need to be managed individually or tailored on a per-patient basis. It is much more difficult for clinical staff to modify thresholds on each patient and then to remember to return these values to defaults based on hospital policies or clinical guidelines. As discussed above, the workflow impacts associated with accomplishing this can be overwhelming to a busy staff and is an unnecessary drain on clinical resources. Limit alarms have their place in identifying deviations of measured patient values against set guard rails based on clinical practice. Yet, limit alarms do not necessarily provide insight into the context of a patient's condition in that measured parameters tend to vary in relationship with one another and it is these interrelationship behaviors that can provide earlier indicators of patient deterioration. [6] [7] [8] [9]

A standard complaint of limit alarms is that they can result in a large quantity of false alarm signal being issued on a patient. That is, the alarm signal exceeds or breaches the established limit threshold but then self-corrects. If the system sensitivity is set so that an alarm will be issued instantaneously when this event occurs, then a large quantity of alarms will likely be issued, most of which are non-actionable (see upper plot of Figure 1). Example causes of these events can include artifact induced by movement of the patient, movement of the sensors (e.g., nasal cannula, pulse oximetry cuffs) and aberrations associated with the equipment (e.g., calibration errors or disconnects). For these reasons, the concept of a sustained alarm is enabled wherein a threshold breach must be continuously maintained for a period of time (some number

of seconds) before an alarm is issued (see lower plot of Figure 1). The logic behind this methodology is that the condition which is causing the parameter to breach the threshold is not aberrant but there is some specific cause that is persistent. The sustained alarm signal can and will result in fewer overall false alarms. Yet, there is also no guarantee that sustained alarm signals will mean there is a clinically-actionable event. The likelihood is greater that there is a correlated cause for the event but it may not be clinically-actionable. An example of a cause that is not immediately detrimental to the patient would be the loosening of a pulse oximetry finger cuff resulting in a poor measurement through the oximeter. Another example would be a kinked tube or a failing measurement sensor in the medical equipment. The cause is certainly actionable in these two cases, but is not necessarily indicative of immediate danger to the patient. On the other hand, the cause may have genuine clinical import, and the sustained alarm notification, because it is based on raw measurements from the device, enables clinical staff to set the sustained alarm limit on the basis of clinical judgment as to actionable level. For instance, an apnea (no breath) alarm may be issued after judging a sustained low or zero respiration rate measurement for 30 seconds.

Related to the sustained alarm is the concept of a trend alarm, in which the trajectory of the measured parameter follows some correlated (i.e., not random) pathway over time. An example of this would be the reduction in respiratory rate or the increase in heart rate associated with respiratory distress. Another example would be the increase in end-tidal carbon dioxide in direct proportion to the decrease in respiratory rate over time. The trended events can be indicative of actionable events associated with a patient based on clinical judgment, and a clinician may opt to be notified of these changes or trajectories over time as there may be clinical significance in understanding the evolution versus simply understanding when a threshold has been breached. By the time a threshold is breached, the reactionary event of an alarm notification will be issued, and depending on the amount by which the breach has occurred, may signal a distressed patient, for example a ventricular tachycardia of 200 beats per minute. On the other hand, if a clinician is notified that the heart rate has been increasing monotonically over some period of minutes, and is provided with a “shoulder tap” (i.e., notification to a mobile communication application and/or visual indicator on a web-enabled display), this type of information can provide valuable foresight enabling the clinician to intervene before the emergent event actually occurs.

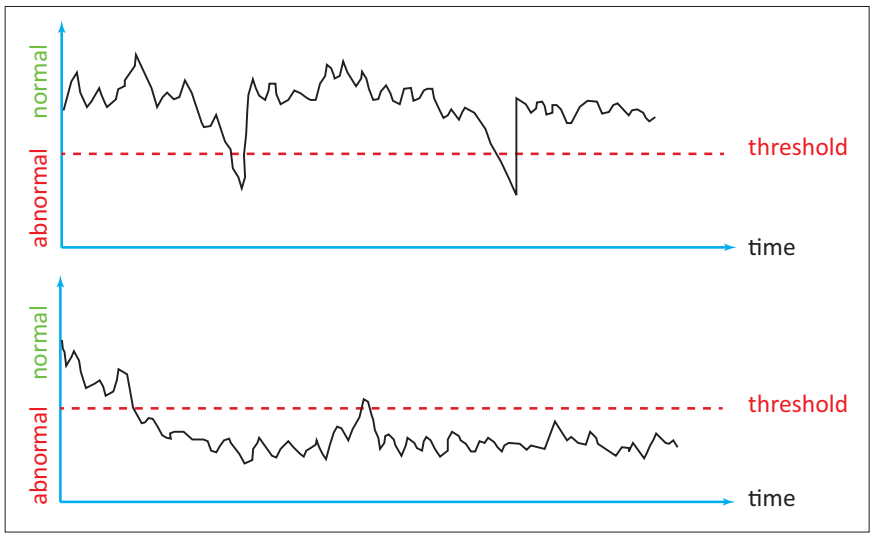


Figure 1: Self-correcting measurement alarm (top) versus sustained alarm.

Detecting Patient Deterioration with Bernoulli Smart Alarms

The various types of smart or user-definable alarm signal settings ("smart alarms") and the flexibility of the parameters surrounding their configuration are a key feature of the Bernoulli One platform. These smart alarms operate on live real-time data as they are collected and enable the platform to issue alarm annunciations that are independent of patient care device (PCD) initiated alarm signals. This feature facilitates customization of alarm settings as well as the creation of signals that are more clinically actionable by placing the power of alarm signal surveillance in the hands of the bedside clinician, enabling them to configure annunciations that are more relevant to their patient cohort, workflow and contextual situation. [10]

Combination Alarms

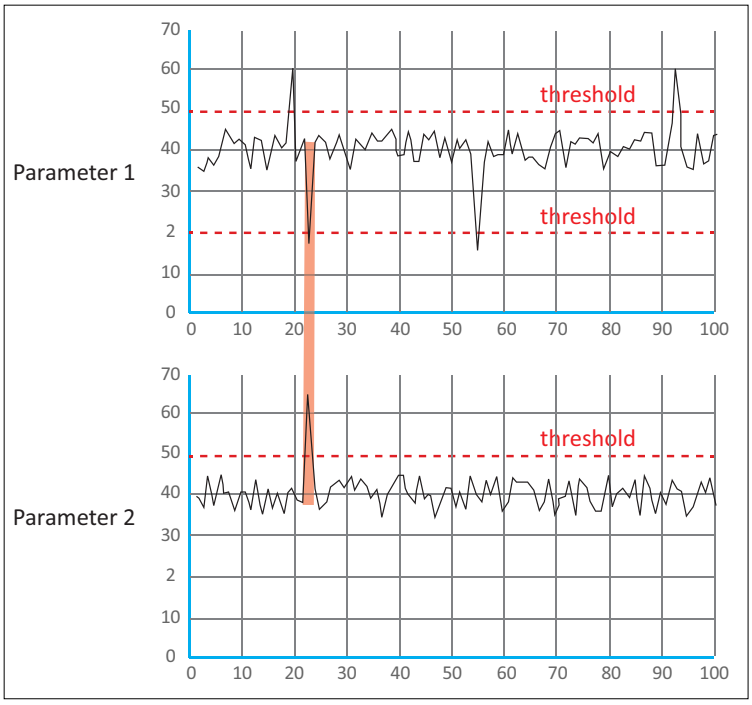


Figure 2: Example of combination alarm signal trigger.

Combination alarms occur when two values (patient measurement) violate their limits, either high or low simultaneously. An example of a signaling condition that will result in the triggering of an alarm annunciation is illustrated in Figure 2. A combination alarm is issued when two or more parameters meet their respective threshold triggering conditions at the same time. The triggering conditions may be simple limit thresholds or the individual parameters may meet sustained criteria where individual parameters meet the limit criterion for a specified duration. Settings associated with a combination alarm include the identification of specific parameters and the limit thresholds associated with each parameter's triggering condition. An example application of a combination alarm would be identifying when patient respirations and end-tidal carbon dioxide meet simultaneous conditions that are indicative of, say, hypoventilation and hypercarbia.

Consecutive Alarms

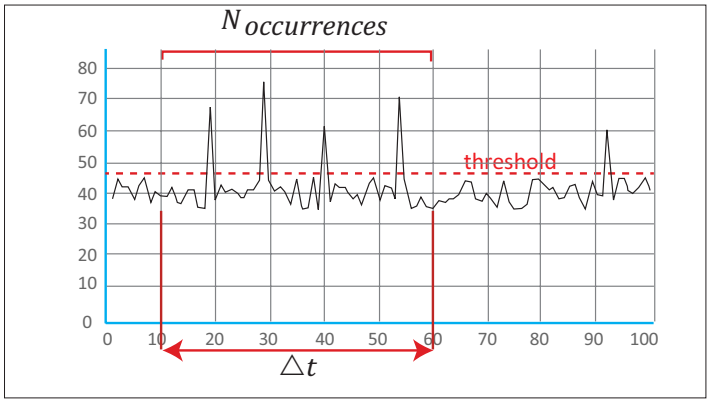


Figure 3: Example illustration of consecutive measurements meeting limit threshold conditions for a specific duration: a consecutive alarm signal trigger.

Consecutive alarms occur when a value (patient measurement) goes in and out of a limit violation a given number of times, over a specific time period, and are events that meet alarm signal triggering conditions within a moving time window (△t). Figure 3 illustrates a condition where a number of measured signal events exceed a given threshold during a given time window. The number of occurrences in which a measurement exceeds a threshold limit within a moving time window are the conditions specified for triggering of a consecutive alarm. An example application of a consecutive alarm signal event condition would be the quantity of peak pressure spikes measured on a mechanically-ventilated patient within one minute's time. When the number of peak pressure spikes exceeds some pre-defined acceptable limit (say, three per minute), this would trigger the issuing of an alarm on said patient.

Sustained Alarms

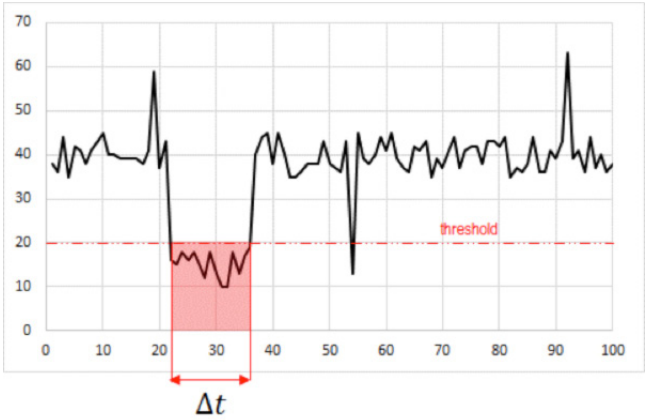
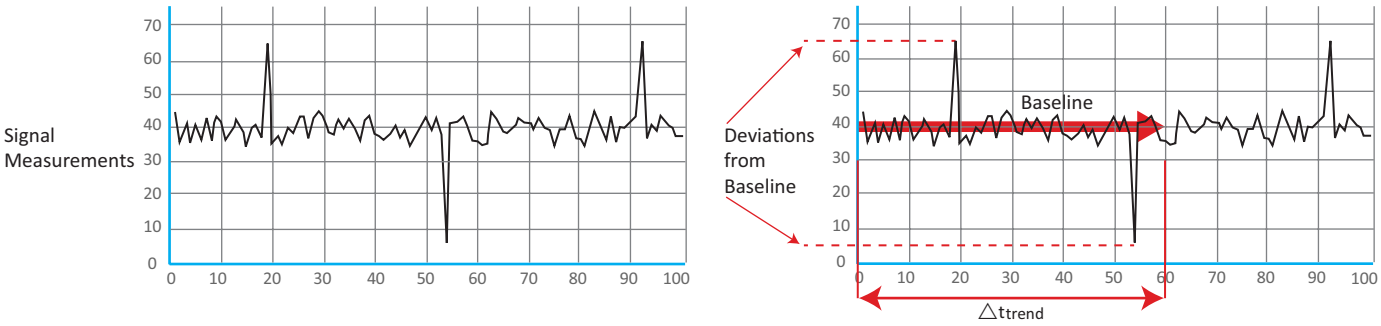


Figure 5: Example illustrating a sustained threshold breach corresponding to the condition required to trigger a sustained alarm.

Sustained alarms occur when a value (patient measurement) violates a specified threshold for a minimum time period, and are those which are triggered when a parameter exceeds a defined signal threshold for a pre-defined time window (△t). Such a condition is illustrated in Figure 5, in which a measurement drops below a defined threshold for a period equal to or exceeding this time window. An example application of a sustained alarm signal event condition would be a sleep apnea alarm, whereby the alarm is not issued until each instance of the measurement of respiratory rate is zero for a predefined period of time (e.g., respiration rate of zero for 20 seconds or more).

Trend Alarms



Trend alarm is issued if deviations from baseline exceed a predefined threshold, defined as a percentage different from baseline (e.g.: 10% deviation)

Trend alarms occur when a given value (patient measurement) violates an upper or lower percentage compared with the average value (normal) for a patient established over a specific baseline time interval ($\triangle t_{trend}$). The amount by which the signal deviates or evolves away from the baseline is defined as a percentage of deviation from the baseline signal, as shown in Figure 6. An example application of a trend alarm signal event condition would be when an adult patient cardiac index (C.I.) deviates from an average baseline of, say, 2 L/min/m2 over a period of two (2) minutes, with an alarm set to trigger when the C.I. exceeds some percentage deviation from baseline (say, 10%). Thus, if C.I. varied by 0.2 over this interval, then a trend alarm would be issued.

Smart Ranked Alarms & Setting Change Alarms

Alarms can be displayed in rank based upon whether they meet criterion for immediacy (i.e., urgency) or warning. The display ranking of alarms in the Bernoulli One dashboard is in accord with the amount by which they exceed specific thresholds assigned based on the other alarm types presented above. This hierarchical display is termed smart ranking of alarms for visual cueing to the clinical end user within the dashboard.

If limit thresholds are changed to a saved setting, such as a bradycardia limit threshold, this will trigger a setting change alarm which is included as a snapshot in the log.

Summary

Because Bernoulli makes use of raw data collected from bedside medical devices and is not solely based on alarms issued by these medical devices, Bernoulli is able to create unique smart alarms that are tailored to the clinical behavior of the patient. Smart alarms are not merely an informational guide to the clinician, but an actionable and interventional assistant for facilitating care.

Bernoulli Smart Alarms:

- Combination alarms facilitate the creation of multi-dimensional parameter alarms, providing the clinician with the ability to create alarms based on the interaction between two or more unique measurements of different parameters from multiple medical devices.
- Consecutive alarms help filter out ordinary non-actionable behavior from potentially chronic and actionable behavior. The benefit to the clinician is a reduced quantity of non-actionable, or "nuisance" alarms.
- Sustained alarms are in some ways similar to those included within certain cardiorespiratory monitoring equipment, in which a known or persistently-occurring measurement is deemed to be actionable when that persistence extends for a specific minimum period of time. For instance, a single parameter threshold breach, such as a bradycardia measurement below, say, 40 beats per minute, would not result in an actionable alarm message, but a sustained set of adjacent measurements of 40 beats per minute for, perhaps, 20 seconds or longer would be actionable in the view of the clinician.
- Trend alarms provide the unique capability of providing notifications when a measurement or set of measurements deviate substantially from a patient baseline. This important capability allows for personalization of the alarm to the specific patient. Deviations are defined with respect to a specific patient baseline, and alarms are issued only when a clinically pre-defined threshold is exceeded over an established duration.

Bernoulli smart alarms can be created, managed and monitored centrally, while notifications for any patient can be routed to a clinician remotely. Because these smart alarm settings are managed through Bernoulli One, they can be established for specific patients or specific departments, thereby mitigating the need to change settings on specific medical devices. This capability aids workflow and allows in-room medical devices to be set in compliance with hospital policy while providing remote monitoring that is tailored to specific protocols or clinical requirements.

Bernoulli smart alarm analytics can be combined together to establish clinically-actionable alarms that identify complex interactions which are not based on only one type of measurement. Specifically, data from other sources, such as inbound laboratory results, can also be used to alter or inform an analytic to provide notifications. For example, the anion ("an-ion") gap calculation, used as part of electrolyte or metabolic panel, involves laboratory determinations of sodium (Na+), potassium (K+), chloride (Cl-), and bicarbonate (HCO3-). It can be employed with measurements of heart rate, blood pressure, and temperature to inform regarding acid-base disorders. Acid-based disorders, in turn, can be used or associated with potential or future onset of conditions such as respiratory compromise and septicemia. Taken together with cardiorespiratory medical device data, anion gap calculation can inform early warning scores. The Bernoulli platform is the only system that supports these capabilities and the ability to create more involved mathematical relationships and analytics that can then be translated into alarms that are in-line with the measurement of medical device data.

Bernoulli enables multiple independent measurements to be correlated and associated with user-defined clinically-significant criteria that, when evaluated together, can yield important early indicators of patient deterioration. This allows hospitals and health systems to develop a comprehensive alarm surveillance strategy that can reduce the risk of alarm fatigue and improve overall patient safety, while also reducing alarm noise at the bedside and improving both patient and staff satisfaction.

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