CARESCAPE Software Platform: Advanced Alarm Algorithms and Configurability Options

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1. THE CHALLENGE OF ALARMS IN A CLINICAL ENVIRONMENT

2015 is the fourth year in a row that clinical alarm hazards lead the list of Top 10 Health Technology Hazard Report published by the ECRI Institute. In the previous years, 2012 - 2014, the report discussed the excessive number of alarms, desensitization of clinicians to the alarms, and consequent alarm fatigue as the cause of the alarm hazards. This year, the ECRI report specifically pointed to "Inadequate Alarm Configuration Policies and Practices" as the top technology hazard.[1]

Alarm configuration practices include determining the alarms that are enabled, selecting the alarm limits, and establishing the default alarm priority levels. These configuration principles are determined based on the care area needs, the type of patients, and the individual needs of particular patients. Inappropriate alarm configuration practices may lead to selection of values or settings that prevent detection of valid alarm conditions (low sensitivity) or expose clinicians to excessive alarms (low specificity). Device manufacturers' responsibility is to provide an intuitive toolset that enables optimal configuration and alarm function.

To understand the factors contributing to alarms and alarm fatigue in intensive care units (ICUs), GE funded an investigator-initiated clinical study carried out by the team of Prof. Barbara Drew and co-workers in the University of California, San Francisco (UCSF).[2]

A total of 2,558,760 alarms occurred in a 31-day study using Solar monitors (2003), and the study concluded that the excessive alarms resulted from "a complex interplay of inappropriate user settings, patient conditions, and algorithm deficiencies."

Both publications provided recommendations for medical teams and for device manufacturers on how to improve alarm configurations based on the needs of the department and the state of individual patients.

2. THE COMPREHENSIVE GE APPROACH

Various components of a monitoring system contribute to the performance of the alarm function. In collaboration with expert clinical teams, GE is working on each component to optimize its alarm performance:

1. Acquisition of each physiological signal is optimized by advanced hardware and software solutions that maximize signal-to-noise ratio and remove both internal and external artifacts.
2. The obtained clean signal is analyzed by a parameter-specific algorithm with high sensitivity and specificity.
3. Information from different parameters is combined for enhanced intelligence and reliability.
4. Advanced configuration tools are provided for alarm thresholds, priorities, and escalation logic to tailor the alarm functions according to the needs of a care area or an individual patient.

In addition, GE is leading the development of clinical guidelines via active participation in standards committees and organizations dedicated to enhanced safety of medical devices.

The CARESCAPE* software platform provides a wide toolset for clinicians to configure alarm thresholds, priorities, and escalation according to the needs of the department and individual patients. With these tools, clinicians can ensure that the alarms given are clinically relevant for the particular patient.

2.1. Algorithm improvements in the CARESCAPE software platform

In various clinical situations, combining information from several parameters helps to create a comprehensive picture of the state of the patient.

CARESCAPE provides the option to automatically select the most accurate source (ECG, SpO_2, Art) for heart rate alarms. This IntelliRate option also provides multi-parameter alarm logic where good-quality Art or SpO_2 measurement may override ECG-based asystole, ventricular fibrillation, or ventricular tachycardia alarm detections.

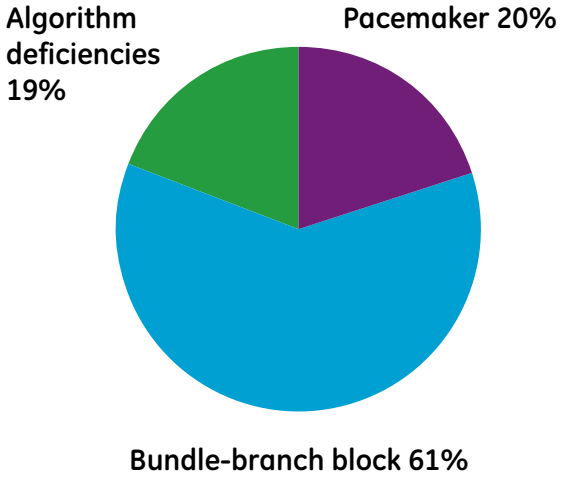
To provide alarms at a priority level that accurately corresponds to the true clinical risk of the patient the CARESCAPE algorithm combines information from parameters such as blood pressure and heart rate, as well as from ECG characteristics. For example, medium-priority alarms for systolic high and systolic low blood pressure alarms are normally given only after a delay of 30 seconds. However, if in addition to systolic high or systolic low condition there is also simultaneously bradycardia, tachycardia, low HR, or high HR present, the algorithm concludes that the situation is more serious and therefore produces a high-risk alarm already in 10 seconds. Various other combinations are also utilized for an accurate risk assessment.

A review of the UCSF study data[2] indicates that 45% of the collected alarms from the 461 patients were for ECG arrhythmia alarms. Analysis of the causes of the false positive arrhythmia alarms resulted in the distribution shown in the pie chart below, where:

- 61% of the false alarms were due to the bundle-branch block in four patients.
- 20% of the false alarms were observed with 20 pacemaker patients, where 66% of such patients did not have the pacemaker setting selected
- 19% of the false alarms were due to algorithm deficiencies.

Out of the 461 patients, 24 were responsible for 81% of the false alarms. In these patients, the alarms could have been avoided by an alarm configuration policy and practice – a finding that strongly supports the ECRI report and recommendations.

Distribution of false alarms in the UCSF study[2] on Solar* monitors



The CARESCAPE software with the EK-Pro v13 arrhythmia algorithm contains performance improvements over the previous versions, including the following:

1. Beat detection: Better performance to detect low and wide QRS complexes. This includes improvements in threshold adaptation especially during a rhythm change.
2. Beat labeling: Improved beat labeling of PVC beats especially with narrow QRS duration. This is particularly important with pediatric patients.
3. Improved artifact filtering in order to better detect arrhythmias in the presence of artifacts.
4. To prevent non-actionable ventricular tachycardia alarms, clinicians are enabled to define the priority level of the ventricular tachycardia event according to the care area or the individual patient. The alarm priority is automatically escalated to a crisis level when conditions warrant.

The impact of these improvements was investigated on the remaining 19% of false alarms, which were related to algorithm deficiencies. The alarms from the ECG signals collected in the UCSF clinical alarm study[2] were reproduced by running the new CARESCAPE software with EK-Pro v13 arrhythmia algorithm on the data. These alarm rates were compared to those obtained using the Solar monitors (2003) with EK-Pro v11 arrhythmia algorithm. The details of the analysis can be found in Reference 3.

According to the results, the new EK-Pro algorithm in CARESCAPE Monitor resulted in a 66% reduction of false arrhythmia alarms compared to the algorithm in Solar monitor, assuming that the clinicians had chosen default alarm settings. The clinicians could have improved the Solar monitor performance by manually adjusting the scale of the ECG signal if the signal was particularly weak. In this case, the reduction of false alarms in the CARESCAPE monitor compared to the Solar monitor would have been 18%. The benefit of the CARESCAPE monitor is that manual adjustment of scaling is not needed to obtain good performance even for low-amplitude signals. No compromises regarding detection of the true events were found.

2.2 Configurable CARESCAPE software platform supports clinicians in following ECRI recommendations

According to the ECRI report, a hospital should establish a policy that describes care-area-specific standard alarm configuration practices. This includes definition of default parameter alarm settings and default volume settings that meet the needs of the specific care area. It is important to clearly establish who is authorized to make particular changes, and to distinguish changes that require a restricted access from those that can be made by nursing staff.

The configurable CARESCAPE software platform supports ECRI recommendations of care-area-specific alarm configuration practices by providing two levels of configuration management:

- Particular features such as default settings are password protected
- Patient specific alarm threshold management is accessible in the alarms setup menu.

As first example of our two level configuration possibilities, the lowest allowable priority level for a tachycardia and bradycardia is defined within the password-protected care unit settings in order to comply with the care unit alarm policy. The priority for tachycardia and bradycardia can then be selected individually for each patient in the alarms setup menu, but it can never exceed the limits defined in the care unit settings. In cardiac units, even minor problems can rapidly escalate to lethal arrhythmias; therefore it may not be advisable to allow for low priority levels. On the other hand, it may be feasible to allow lower priorities to be selected in general wards. Many characteristics of the care area, such as the nurse-to-patient ratio, may also affect the choice of departmental configurations. Lowest allowable priorities for SpO_2, impedance respiration, and other parameters have been implemented in CARESCAPE according to this same logic.

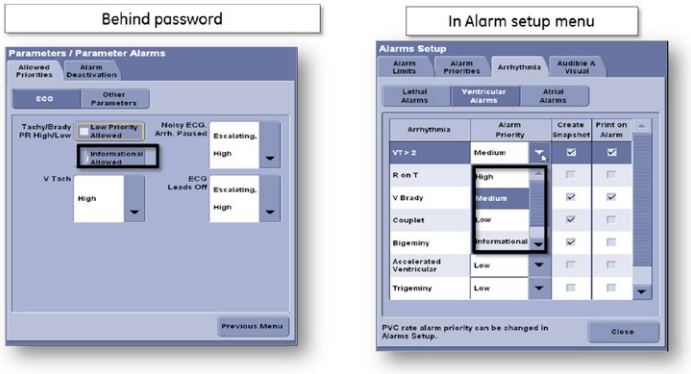


Figure 1. The setting of the lowest allowable priority for an alarm is password protected (left), while clinicians can set the alarm priority for an individual patient in the alarms setup menu (right) within the allowable limits.

As second example of our two level configuration options, the deactivation feature of technical and parameter alarms in CARESCAPE monitors supports the policies of different care units. Accidental disconnection of a measurement (such as a dislodged SpO_2 probe, ECG lead or invasive pressure line) disables the measurement, and the monitor provides a technical alarm so that the clinicians are informed to correct the situation. There are, however, situations in which a measurement is temporarily disconnected due to a care procedure, or permanently stopped if there is no longer a clinical need to continue the measurement. These types of alarms would increase alarm fatigue if they were not user configurable, and possible for the caregiver to silence and acknowledge. The hospital unit may allow deactivation of technical alarms under a password-protected setting, so that the nurse can deactivate the technical alarms in these situations.

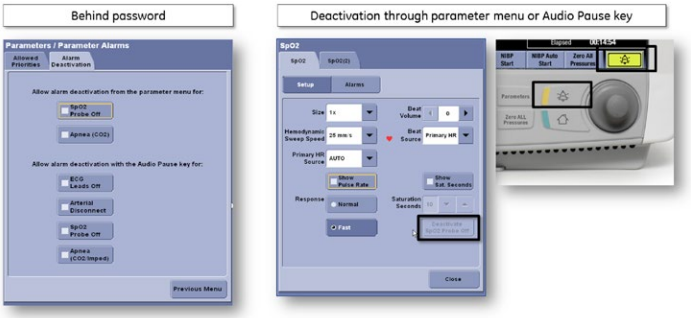


Figure 2. The hospital unit may allow for technical alarm deactivation (left), which then enables clinicians to deactivate these alarms when the disconnection of a measurement is due to a care procedure.

The table below summarizes the alarm features of CARESCAPE monitors that have been designed according to this two-level structure recommended by ECRI.

Two-level configuration structure in GE CARESCAPE:

Condition	Password-protected	Available in alarm setup menu
Non-lethal arrhythmia alarms	Lowest allowable priority	Priority for an individual patient
Alarm for SpO_2 low	Lowest allowable priority	Priority for an individual patient
Alarm for SpO_2 probe off	Lowest allowable priority	Priority for an individual patient
Alarm for respiration impedance	Lowest allowable priority	Priority for an individual patient
Deactivation of technical alarms	Deactivation allowed/not allowed	Deactivation
Change telemetry battery	Not applicable, no password protection	Priority for an individual patient
Alarm volumes	Volume setting separation based on alarm priority level	Own volume control for higher/lower priority alarms
Remote alarm management	Allowance to pause an audible alarm from a remote location	Possibility to pause audible alarm remotely

In addition to the priority levels of high/medium/low, the CARESCAPE software platform enables configuration of an alarm to a lower "Informational message" level. This option can be used for non-lethal arrhythmias, impedance respiration apnea, or change of a telemetry battery. An informational message is neither sent to the network nor latched. The principles of the different priority levels of alarms are listed in the table below.

Priority levels of alarms:

Signal	Priority Level			
	High	Medium	Low	Informational
Alarm area	White text inside a red box	Black text inside a yellow box	Black text inside a blue box	Black text inside a grey box
Audible tone pattern	Repeats pattern of 2 x 5 beep tones	Repeats pattern of 3 beep tones	1 beep tone	None
Audible tone pattern (legacy)	Repeats pattern of 3-beep tones (crisis)	Repeats pattern of 2-beep tone (warning)	1 beep tone (advisory)	None
Alarm light indicator	Flashes red	Flashes yellow	Solid blue	No effect

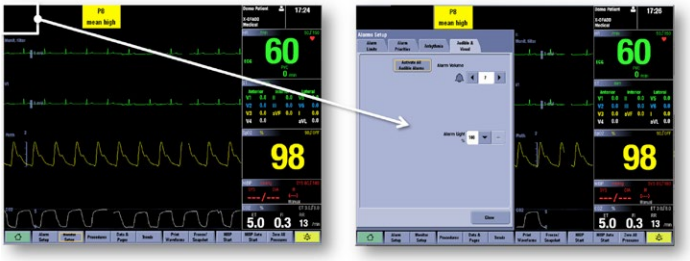
ECRI recommendations also include the practice of reactivating the care-area-specific default alarm settings whenever a new patient is connected. CARESCAPE automatically restores these default settings for a new patient.

The volume and sound pattern strongly affect the perception of an alarm. The configuration of volume settings for the particular care area was specifically brought up in the ECRI recommendations, where the CARESCAPE software platform allows various configuration options. A low-priority tone can be configured to be either a single or a repeating tone. The volume can be set to be similar for all the priorities, or a different volume for low priority can be chosen. CARESCAPE monitors also allow also the ability to remotely pause audible alarms. Users can define and select which remote locations are allowed to pause audible alarms on the monitor: "Only central," "Both central and remote beds," or "None". For safety reasons, this selection is password-protected.

To enable hospitals to incorporate alarm configuration protocols and procedures according to ECRI recommendations, it is vital that the monitoring system supports easy access to all the functionalities. With a CARESCAPE monitor, the clinician only needs to touch the upper left corner, the alarm icon location of the screen to open the Alarms Menu and provide a quick access to alarm menus and functions:

- Audible & Visual for alarm silencing
- Alarm Limits for alarm limit changes
- Alarm Priorities
- Arrhythmia tabs for further alarm configurations.

Fast access to alarm silencing and other alarm controls:



In addition, the ECRI recommendations include various other important aspects around education and training of clinical personnel.

For further configuration options please refer to the latest CARESCAPE Modular Monitors User's Manual software version 2.

3. SUMMARY

False alarms constitute a multilevel problem, from reliable signal acquisition, to the interaction of the caregiver with the monitoring system, which enables optimal configuration for a department as well as for individual patients. It is the responsibility of the monitoring system manufacturer to develop technologies that support every level of alarm performance. This article presented some recent advancements implemented in the CARESCAPE monitor software platform. GE is committed to continuing development work in collaboration with clinical expert teams to achieve continual improvement.

REFERENCES

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2. Drew BJ *et al.*: PLoS ONE 2014; 9(10): e110274
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