

mysafety insight

CrozFusion™

Clinical Information Leaflet

Confronting Alarm Hazards

The Impact of Alarm Hazards

The purpose of clinical alarms in medical devices is to enhance patient safety. By alerting caregivers to changes in a patient's condition, alarms highlight that action may be needed to avoid patient deterioration.

By design, alarms are highly sensitive, so important events are not missed. However, this high sensitivity can cause many false alarms, which in turn leads to alarm fatigue in caregivers.

When alarms are configured correctly and managed well, false alarms are reduced and patient care is enhanced. When alarms are managed badly the opposite happens. Caregivers become overwhelmed and desensitized by the number of alarms, which can lead to missed alarms and delayed responses. Alarms that are ignored can and have resulted in patient deaths^[1].

In 2012, the ECRI Institute listed Alarm Hazards as the No.1 Health Technology Hazard^[2]. Still in 2020, cognitive overload from alarms remains in the top 10 health technology hazards by ECRI^[3].

Between 2005 and 2010, at least 216 deaths across the United States were linked to unheard or dysfunctional alarms^[4]. Also, between 49% and 96% of clinical alarms get overridden^[5]. Alarm fatigue triggered by too many alarms that are irrelevant, not serious, or repeated is one of the primary reasons why caregivers override them. Another likely contributor to alarm fatigue is cognitive overload, where alerts are complex, repeated and received without the necessary resources to deal with them^[5].



Top 10 Hazard

voted as one of Top 10 Health Technology Hazards of 2020 by ECRI



942 alarms each day

in a typical 15-bed unit



1 alarm every 90 seconds



90% alarms are unanswered



216 deaths

occurred during 2005 and 2010 in the USA related to alarm fatigue, according to FDA's database



Imaging your phone ringing 350 times a day. We try to reserve alarms for the most important, actionable events.

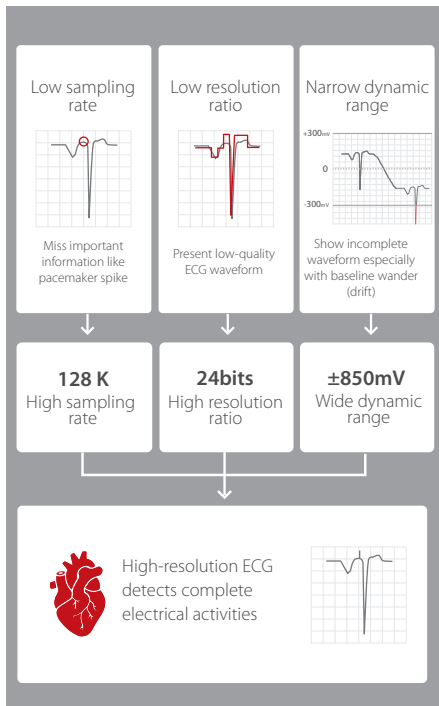


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Johns Hopkins Hospital

Innovative False Alarm Reduction

1. High resolution data:

Mindray' powerful hardware platform provides caregivers with advanced monitoring parameters of refined accuracy and high-fidelity data. For higher accuracy ECG analysis, Mindray patient monitors utilise the same data acquisition and processing technology used in specialized, standalone ECG cart devices, providing a higher sampling rate for pace detection, higher resolution and a wider dynamic range.



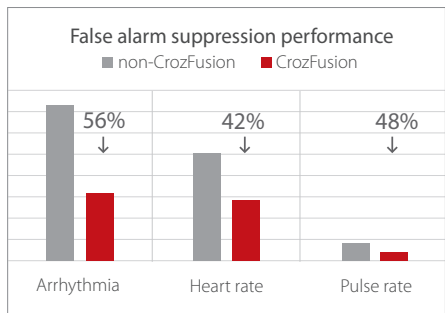
2. Fusion algorithm analysis:

ECG and SpO₂ are usually measured independently at different parts of the body. If interference, noise or adjustments are made, it often happens in a localized area and will usually only affect either the SpO₂ or the ECG. Mindray CrozFusion™ technology uses a unique algorithm to recognise the signal strength of ECG and SpO₂, categorizes them into different levels of signal strength (SQI: Signal Quality Index), and suppresses false alarms caused by signal noise [6,7].



3. Informed decision-making:

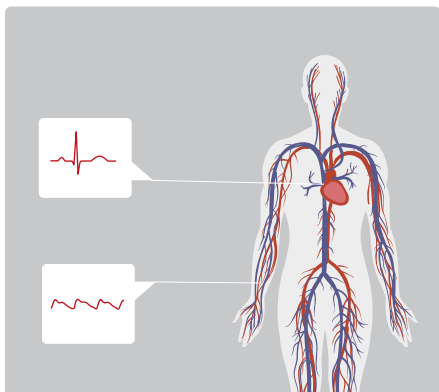
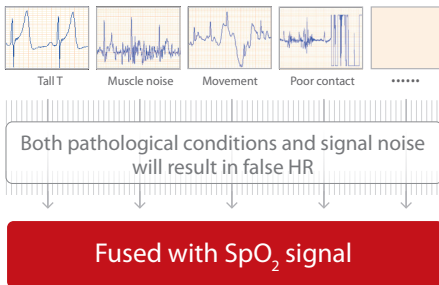
With high-resolution raw data and CrozFusion algorithm, the monitor filters a large amount of false alarms and helps caregivers focus on the most meaningful information. Mindray's unique 4-lead ECG simultaneous arrhythmia analysis algorithm, also helps to further suppress unnecessary alarms [8].



These results are based on a Mindray multi-center clinical study involving more than 2800 patients including adults, infants and neonates in CCU, PICU and NICU settings.

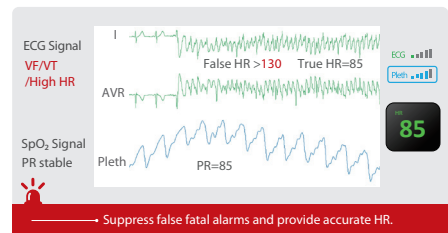
Simpler and Smarter Solutions

After many years of research and over 4300 clinical tests, Mindray has successfully developed CrozFusion which is able to increase the noise immunity of ECG arrhythmia analysis by fusing its decision with blood oxygen saturation (SpO₂) measurements, thus effectively suppressing false alarms. According to the relationship of homologous physiological signals (ECG and SpO₂), comprehensive analysis of these signals identifies the false alarms and improves the performance.

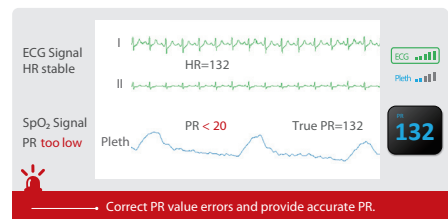


When CrozFusion is activated, the Signal Quality Index (SQI) indicators for ECG and SpO₂ are displayed on the patient monitor. Below are some scenarios of how CrozFusion works:^[6,7]

1. If both SQIs for ECG and SpO₂ are high, CrozFusion will not intervene.
2. In case 1 below, the ECG SQI is poor and heart rate (HR – taken from ECG) appears to be higher than the pulse rate (PR – taken from SpO₂). CrozFusion identifies the false HR, caused by signal noise, and combines the ECG with SpO₂ to count the accurate HR. In this case, the true HR value actually comes from PR.
3. In case 2 we see the opposite: the SpO₂ SQI is poor and the PR is very low. The algorithm detects the suspect PR, caused by patient movement, and responds by combining the SpO₂ with ECG to count PR. In this case, true PR value on the monitor actually comes from HR.



Case 1: HR fused by PR



Case 2: PR fused by HR

Fewer False Alarms with Uncompromised Accuracy

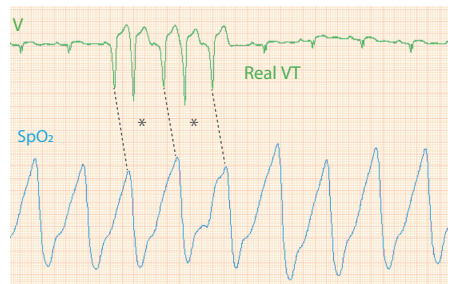
Thanks to Mindray's sophisticated CroZfusion algorithm, Mindray patient monitors can effectively reduce false alarms while also guaranteeing that real arrhythmias will not be missed.

For example, in the cases below, both ECG waveforms look like that ventricular tachycardia occurs. Let's take a look at how CroZfusion behaves:

1. In case 3, although the ECG waveform does not fully correlate to the pulse waveform - only every second premature ventricular contraction (PVC) is matched with a pulse wave (other PVCs marked with * result in undetectable pulses), the ECG is identified with good signal quality. After analysing, CroZfusion triggers a VT alarm as the ECG waveform has been validated as an reliable signal.

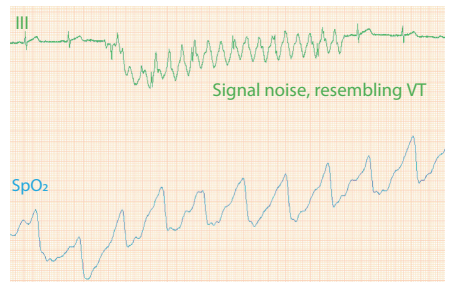
2. In case 4, the ECG is identified with poor signal quality and the PVCs cannot be matched with the pulse waveform. This time, CroZfusion recognises the artifact (noise) by cross-checking ECG against the SpO₂ and avoids triggering false VT alarm.

Pathological abnormal ECG



Case 3: CroZfusion™ enhances the ability to detect real arrhythmias.

ECG interfered by artifact



Case 4: CroZfusion™ decreases false arrhythmia alarms.

Note: In the following situations, CroZfusion must be disabled: performing CPR, CPB, ECMO and IABP therapy.

CroZfusion, Mindray's unique alarm management solution, forms a core part of the BeneVision N Series and ePM monitoring solutions. By reducing false alarms, CroZfusion is helping reduce alarm fatigue, improve staff efficiency and enhance patient safety.

References:

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- [2] Biomedical Safety & Standards, 2012. ECRI's Top 10 Health Technology Hazards for 2012. *Biomedical Safety & Standards*, 42(2), pp.9–10.
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- [6] Sun, Z. et al., 2014. Reducing ECG alarm fatigue based on SQI analysis. *Computing in Cardiology*, 41, pp.345–348.
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