Clinical alarms & fatalities resulting from ‘alarm fatigue’
in hospitals: perspectives from clinical medicine, acoustical
science, signal processing, noise control engineering & human
factors

“It’s more than a nuisance”
James Blum MD, University of Michigan Health System

“This is a signal-to-noise problem”
George Blike MD, PhD, Dartmouth-Hitchcock Medical Center

By:
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Problem: Alarm fatigue is recognized as a serious, life-threatening problem in hospitals and
healthcare facilities. It is experienced by patients, physicians, caregivers and families—indeed
everyone within hearing distance. Alarm fatigue is caused by multiple, frequent, uncorrelated and
highly arousing noises from alarms and other sources. These noises mix and reverberate in
rooms that are characterized by a preponderance of hard, non-sound-absorbing, highly-reflective
surfaces and high levels of 24/7 activity. For example, in acute care settings such as operating
rooms there may be as many as 120 separate alarmed devices that are stand-alone,
uncorrelated and un-prioritized. Alarm fatigue can occur in many settings in a hospital including
ER, OR, NICU, ICU, nurse stations, patient rooms, etc.

Context: In 2011, the Joint Commission, the U.S. Food and Drug Administration and the ECRI
Institute, following an independent analysis of FDA incident reports, disclosed over 500 patient
deaths in hospitals resulting from alarm fatigue and designated alarm fatigue a top priority. On
October 4-5, a national summit on alarms was held in Washington DC co-hosted by the Joint
Commission (which licenses U.S. hospitals), the U.S. Food and Drug Administration (which
regulates medical devices), the ECRI Institute and the American College of Clinical Engineering
(ACCE), and the Association for the Advancement of Medical Instrumentation (AAMI) which
organized the summit. The summit gathered 300 professionals and stakeholders to hear case
studies and consider courses of action. Several of the authors were invited to: (a) participate in
planning the summit; (b) give plenary presentations; (c) designate a representative to participate
in the post-summit continuing committee; and (d) participate in the development of an IEC/ISO
standard for clinical alarms.

Causes & effects: Codes and standards require that alarm signals be loud enough to be heard
above background noise. However, in hospitals noise has grown steadily for decades and now
typically averages 50-60 dB*—significantly louder than levels recommended by the World Health
Organization, the American Hospital Association and others. Unfortunately, the signal to noise
ratio (s/n) required by standards to set alarm levels—when used in hard-walled, reverberant
spaces—produces a feedback loop in which noise levels steadily increase. In these extremely
noisy and distracting conditions any or all of the following can occur, posing threats to patient health and well-being:

- impaired communication and concentration;
- disorientation and distraction;
- elevated blood pressure and stress that leads to fatigue;
- auditory habituation or ear fatigue (desensitization that interferes with hearing);
- increased error and patient harm rates;
- potentially dangerous, life-threatening behaviors (such as turning off alarms);
- for patients, bodily harm and loss of sleep that is essential for healthy recovery;
- startle-response, an array of symptoms that exacerbate patients’ conditions.

**Standards & codes:** Three standards relating to alarm signals are recognized by the U.S. Food and Drug Administration:

- IEC/ISO 60601-1-8:2006 Ed.2: Medical electrical equipment, Part 1-8: General requirements for safety – Collateral standard: General requirement, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems;
- ANSI HE75: 2009, Human factors engineering – Design of medical devices; and
- IEC62366, Medical devices – Application of usability engineering.

Standards and guidelines relating to alarms and ambient noise levels in health care facilities can be found in the 2010 FGI Guidelines which is accepted as code by most States and 16 foreign countries, and by FGI’s reference document, Sound & Vibration Design Guidelines 2.0 (2010), both of which are published by the Facility Guidelines Institute and the American Hospital Association’s ASHE division. These two documents are referenced in the Joint Commission report Planning, Design, and Construction of Health Care Facilities, 2nd Edition (2009), and the U.S. Green Building Council’s new LEED Rating System for Health Care (2011).

In addition, a new IEC standard is in draft: IEC 80001-2-x: Application of risk management for IT-networks incorporating medical devices – Part 2-x: Guidance on the integration of alarms. Two of the authors of the white paper are involved in the development of this standard (Sykes, Xiang).

**Recent case studies:** Numerous case studies demonstrate methods for significantly reducing noise and alarm fatigue through changes to culture, procedures, maintenance and simple modifications to the physical environment to reduce ambient noise levels that establish the threshold for the signal-to-noise ratio (s/n) that is the basis of the problem of alarm fatigue. Some of these methods include:

1. Reducing noise levels in patient rooms by centralizing alarms at nurse stations;
2. Changing the signal to noise ratio (s/n) by adding sound absorptive material to room surfaces which reduces overall noise reverberation and enables alarm loudness levels to be lowered;
3. Installing multi-parameter alarm integration devices to reduce the number of separate and uncorrelated devices with alarms;
4. Using visual alarms & displays (for example, outside patient rooms) to reduce dependence on bedside alarms;
5. Deploying secondary notification systems (e.g., pagers or smart-phones) managed by telemetry;
6. reducing the incidence of nuisance alarms and false positives through various methods including maintenance and procedural changes.

**Solving the alarm fatigue problem starts with detailed, trans-disciplinary analysis:** Healthcare professionals, designers & engineers of healthcare facilities, clinical engineers, and developers of medical devices who are seeking practical ways to reduce or eliminate alarm fatigue should use the comprehensive systems analysis method for analyzing noise problems
called “Source-Path-Receiver.” This trans-disciplinary, inter-departmental approach provides detailed insight into noise problems from all of the perspectives required to address alarm fatigue. For example:

**Sources** - e.g., planning and specification of paging systems, clinical and monitoring alarm systems, HVAC/air flow equipment and other building MEP systems, location of gathering places such as nurses stations where unamplified human speech occurs, use of alarm sounds that are optimized for informational content, urgency mapping, audibility and localizability, and all other noise sources and audio equipment;

**Paths** - e.g., adding sound absorptive material to room surfaces and designing sound paths to minimize excessive alarm signal levels at receptor sites and to prevent sound mixing and reverberation and the like;

**Receivers** - e.g., modifying traffic flow and other behaviors through architectural and equipment layouts to ensure that physicians, caregivers and patients can hear and respond to alarm signals without being distracted, confused and fatigued by high levels of ambient noise.

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1 Invited delegates from the acoustical science community to the national summit on medical device alarms, Washington DC, October 4-5, 2011.

2 Case studies and research were described at the national summit on medical device alarms in Washington DC, hosted by US FDA, the Joint Commissions, the ECRI Institute, the American College of Clinical Engineering, and the Association for the Advancement of Medical Instrumentation on October 4-5, 2011. Ten cases at the following institutions were described by presenters: Johns Hopkins Hospital, Massachusetts General Hospital, Childrens' National Medical Center, Dartmouth-Hitchcock Medical Center, UCSF & Stanford Medical Center, University of Miami, University of Michigan Health System, Boston Medical Center, William Beaumont Hospital, and Yale University School of Nursing. See: [http://www.aami.org/alarms/materials.html](http://www.aami.org/alarms/materials.html)

3 A monaural analytical model that allows alarm noise to be assessed against background and other noises was described in the journal *Applied Acoustics*. Available software includes modeling of the auditory filter and other factors involved in the audibility of alarms. A binaural noise analysis model has been developed at Rensselaer Polytechnic Institute.

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