FRESENIUS KABI

Infusion Pump Alarms

Helping to Improve Intravenous Therapy:

Opportunities for Designing the Next-Generation Infusion System

Authored by

MATTHEW B. WEINGER, MD, MS
ANDREW KLINE, BA
Department of Anesthesiology,
Vanderbilt University School of Medicine.

IVENIX
INFUSION SYSTEM

INFUSION PUMP ALARMS MANAGEMENT

In this whitepaper, we strive to provide an overview of the current status and apparent effectiveness of infusion pump design from the end user's point of view. We acknowledge the advances in the field while highlighting opportunities for future improvements. In focusing on some of the usability issues of current pump interfaces and insufficient interoperability, we highlight some of the existing pitfalls and offer human factors-based guidance for next-generation designs. Here, we define infusion pump usability as the relationship between the technology and clinicians' ability to use that technology to help attain their work goals effectively, safely, efficiently, and with both clinician and patient satisfaction.

Further, we will focus on infusion pump alarms management.

> "In focusing on some of the usability issues of current pump interfaces and insufficient interoperability, we highlight some of the existing pitfalls and offer human factors-based guidance for next-generation designs."

Alarms Management – Too Much Data, Not Enough Actionable Information

A 2013 national survey by the Physician-Patient Alliance for Health and Safety (PPAHS) found that alarm fatigue was a top concern at 19 of 20 U.S. hospitals. In fact, 87.8% of respondents felt that decreasing the incidence of false alarms would increase the use of medical devices.[1] Because infusion pumps are one of the most widely used medical devices, better pump alarms could help to drive analogous alarm improvements across the device industry. Alarm fatigue continues to plague front-line users in hospital systems worldwide. Thus, alarms are frequent and, more often than not, clinically insignificant, causing caregivers to develop alarm desensitization and to be more likely to ignore the clinically important alarm.[2] Since 2015, ERCI Institute has called clinical alarms the most hazardous health technology, citing the many incidents in which alarms were either missed or responded to too late.[2] Note that because clinicians are only rarely looking at any one device, here we are talking mostly about auditory as opposed to visual alarms.

Infusion pump alarm tones are often indistinguishable from those of other devices in patient care areas. The 2010 AAMI/FDA Infusion Device Summit, attended by over 300 physicians, nurses, clinical engineers, human factors engineers, regulators and other key stakeholders, emphasized

the importance of standardizing alarms and ensuring that alarm tones are meaningful, informative, not stress inducing, and of appropriate volume/saliency for the clinical context.[3] Better discrimination of the nature and criticality of an alarm could potentially enhance users' response to critical alarm conditions. Device manufacturers typically assume that their device will be at the clinicians' "center of attention." Audible alarms, often containing no useful information other than an attempt to garner attention and signal "look at me," are then associated with a visual alarm that contains additional information.

Alarm and device standards require three levels of alarm "priority" — high, medium, and low — each associated with a different audible tone. Design decisions about alarm priority should be based on a rigorous use-related hazard analysis.[4] Unfortunately, infusion pump alarms can contribute to potentially high incidence of alarms, including false alarms at the bedside. A clinician, surrounded by numerous similar sounding beeps, can have difficulty ascertaining if a critical event has occurred. Instead, their reaction to an alarm sound becomes "turn it off!" instead of "what is the problem?" Over-worked and distracted caregivers are thus known to inappropriately adjust alarm limits or lower alarm volumes to try to reduce the noise pollution in their workspace.

Next steps should involve initiatives to diminish the number of insignificant pump alarms and to ensure that alarms of a critical nature are distinguishable. A user-centered systems approach would allow an array of alarm-enabled devices to communicate with each other seamlessly to help identify, reduce, and provide the information available about true alarms.

Eliminating Unnecessary Alarm Conditions

Eliminating unnecessary alarm conditions would go a long way to reducing the alarm fatigue problems. For many clinicians, the most dreaded infusion pump alarm is the "air in the line" alarm, which can delay therapy. Priming and removing air from infusion tubing can be time consuming and distracting from other high priority clinical tasks. It is time consuming and distracting from other higher priority clinical tasks. Why can't a pump automatically prime and remove all air from the infusion tubing before initiating the programmed therapy? The length/volume of infusion tubing is typically a known quantity (at least with cassette-based administration sets) and air-eliminating filters have established efficacy and safety. During infusion therapy, air generated by outgassing should be automatically and safely eliminated instead of necessitating that a nurse return to the bedside to "get the air out."

Other opportunities for reducing alarm conditions include more intelligent approaches to infusion management such as being able to infuse until a bag is empty rather than requiring the clinician to set a Volume to be Infused (VTBI) manually, automatic back-priming of secondary infusions and intelligent detection and management of downstream occlusions — e.g., intermittent occlusions due to transient conditions such as bent arms or inflated non-invasive blood pressure cuffs.

> "For many clinicians, the most dreaded infusion pump alarm is the "air in line" alarm."

DESIGN RECOMMENDATIONS
Alarms

- *Better alarms.* Every infusion pump alarm should be informative (i.e., tell the user what the pump thinks is happening), and actionable (tell the user what to do to rectify the situation).
- *Alarm integration.* Infusion pump alarm systems should be integrated across all pumps in use on the same patients thereby enhancing clinicians' overall situation awareness and their ability to appropriately prioritize multiple alarm conditions.
- *Pump-to-pump and pump-to-device communication.* Infusion pump systems should be able to communicate bi-directionally with other medical devices expected to be attached to the same patient so as to share useful information related to alarm conditions including guidance to the user regarding alarm condition cause and appropriate response.

References

1. Wong M, Mabuyi A, Gonzalez B: First National Survey of Patient-Controlled Analgesia Practices. In: Presented at the Society of Anesthesia and Sleep Medicine Annual Meeting: 2013; San Francisco, CA; 2013.
2. ECRI Institute: Top 10 Health Technology Hazards for 2015. Reprinted from Health Devices, November 2014, 33 pp. Accessed at www.ecri.org/2015hazards
3. Association for the Advancement of Medical Instrumentation (AAMI): Infusing Patients Safely: Priority Issues from the AAMI/FDA Infusion Device Summit.

   In: AAMI/FDA Infusion Device Summit: 2010; Silver Spring, MD: AAMI; 2010.
4. American National Standard Institute: Human factors design process for medical devices. In: Planning the HFE Process. Association for the Advancement of Medical Instrumentation (AAMI); 2009.

FRESENIUS KABI

Fresenius Kabi USA, LLC
Three Corporate Drive
Lake Zurich, IL 60047
Phone: 1.888.386.1300
www.fresenius-kabi.us/ivenix

3558-IVEN-09-02/23 v2.0