IMPROVING MEDICAL ALARM SYSTEMS
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Signal to Noise

When we decided to tackle the issue of alarm safety in healthcare, we knew it was a big issue. We had no idea how big until we started building the table of contents for this issue of *Horizons*.

“Signal to noise” has become my personal catchall phrase for the issues with alarms. Aside from the strictly engineering definitions of signal to noise ratio, *PC Magazine’s* encyclopedia explains that as a metaphor, “signal to noise” is “used in chat rooms and Usenet discussions to refer to meaningful discourse (signal) to worthless blather (noise).”

I’m reminded of the alarms in my own life. It’s 2 a.m., and my cell phone, charging in the bathroom, sounds an alarm to alert me to an incoming text message (probably from my 24-year-old daughter). In a sleep-induced fog, I hear the noise and shuffle in to turn off the phone without even looking. Early the next morning, at about the same time, my wake up music alarm goes off, the neighborhood dogs start their morning chat, someone’s car alarm goes off, and the garbage truck bleeps out alarm noises. Later that day in the office, I’m completely absorbed in a big project and don’t even hear the 15 minute premeeting alarm on my computer, alerting me to an important conference call. These alerts and noises are so common on my crammed calendar, overly active cell phone and in my hectic life that they just aren’t effective at telling me something really important. My overloaded, middle-aged brain shuts them off.

I recently toured a major hospital to see a gorgeous new patient floor. The technology was amazing. At the same time, my heart went out to the nurses. How can they possibly provide patient care while at the same time being a master at all of this new technology (on top of the noise already in their daily lives away from the patient floor)? I can’t manage the alarm noise in my own life, so the thought of hearing hundreds of alarms a day in a pediatric unit makes me gasp.

With that backdrop, we want to salute the work of nurses, the unsung, noise-cluttered heroes whose unending commitment to patient well-being deserves our determination to solve the issues with alarms. We challenge the entire healthcare community to embrace a powerful mission for alarm safety: **By 2017, no patient will be harmed by adverse alarm events.**

At press time, AAMI is in the early planning stages for a multi-disciplinary alarm safety summit that will be held October 4-5, 2011 in Herndon, VA (see www.aami.org/alarms). Our inspiration and theme will be the above vision for a safer future with alarms.

The outstanding articles in the pages that follow will help guide us in planning that event. In the meantime, we trust that these articles will help you solve some particularly vexing and immediate alarm issues that can’t wait. We also believe this collection of wisdom from experts, plus knowing we are doing a summit, will give you hope that we will be able to celebrate a great achievement in the year 2017: no patient will be harmed by adverse alarm events. I look forward to sharing a toast with you that year.

Mary K. Logan, JD, CAE
President, AAMI

About This Issue

This issue of *Horizons*, a special, one-time magazine, focuses exclusively on improving medical alarm systems which warn of danger by alerting caregivers to critical medical information. The latest in a series of special *Horizons* publications released by AAMI, it examines how to improve the safety and effectiveness of such systems.

Founded in 1967, AAMI is a unique alliance of more than 6,000 members united by the common goal of increasing the understanding and beneficial use of medical instrumentation.
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ACCE is committed to enhancing the profession of clinical engineering. With members in the United States and abroad, the ACCE is the only internationally recognized professional society for clinical engineers. Visit www.accenet.org.

The Association of Surgical Technologists
As the oldest and most widely recognized professional organization for surgical technologists and surgical assistants, AST’s primary purpose is to ensure that surgical technologists and surgical assistants have the knowledge and skills to administer patient care of the highest quality. Visit www.ast.org.

ECRI Institute
ECRI Institute is an independent nonprofit organization that researches the best approaches to improving the safety, quality, and cost-effectiveness of patient care. Visit www.ecri.org.

The Infusion Nurses Society
The Infusion Nurses Society (INS) is committed to bringing innovative new resources and opportunities to a wide range of healthcare professionals who are involved with the specialty practice of infusion therapy. Visit www.ins1.org.

The Institute for Safe Medication Practices
The Institute for Safe Medication Practices (ISMP), based in suburban Philadelphia, is devoted to medication error prevention and safe medication use. It represents over 30 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process. Visit www.ismp.org.

National Patient Safety Foundation
The National Patient Safety Foundation has been pursuing one mission since its founding in 1997 – to improve the safety of care provided to patients. As a central voice for patient safety, NPSF is committed to a collaborative, inclusive, multi-stakeholder approach in all that it does. Visit www.npsf.org.

In This Issue

Alarm systems and ventilators in critical care are the subject of a new international standard, page 54.

Alarm systems in the home environment pose special challenges, page 10.

Research on cardiopulmonary monitors and clinical significant events in critically ill children, page 38.
Medical device alarms provide essential warnings to alert caregivers of changes in a patient’s condition. When alarms work well, the environment of care is enhanced. When alarms don’t work well, they pull caregivers away from other duties and other patients—or worse, train caregivers to ignore the alarm sounds altogether. Alarms that are ignored can and have resulted in patient deaths.

Today, by and large, medical device alarms don’t work well. Too many devices sound too many alarms and are wrong too often. Why is that, and what can be done about it?

**The Problem**

As the number of devices in patient care areas have multiplied, so have the noises they make. Experts say that most alarms generated by medical devices don’t require any action at the bedside—from 85% up to 99%. These “nonactionable” alarms add to the noise, confusion, and stress in an already-stressful environment.

High false alarm rates intertwine with other alarm problems including:
- Alarms parameters often are not properly customized to individual patients or patient environments.
- Alarms from individual devices are not integrated with those from other devices in the same area.
- Components in the signal path—sensors, cables, lead wires—may fail intermittently.
- Legal liability concerns cause a strong bias toward false positives rather than false negatives.
- Confusing alarm sounds don’t convey needed information to users.

**Possible Solutions**

Some facilities have had astounding success at improving alarm performance. Dartmouth Hitchcock Medical Center in Lebanon, NH, undertook an alarms improvement initiative on a post-surgical orthopedic floor. It succeeded in reducing the average number of alarms per patient per day to only four. William Beaumont Hospital in Detroit, MI, reduced its mean alarm response time on a telemetry floor from 9.5 minutes to 39 seconds by implementing a new communication system. Johns Hopkins Hospital in Baltimore, MD, revamped alarm procedures in a medical step-down unit and achieved a 43% decrease in critical alarms.

Experts agree that resolving problems with medical device alarms requires interdisciplinary effort and buy-in from a wide array of players at the highest levels. They also say that technology—the very devices that sound these alarms—can be used to alleviate the problems they have created.

What can be done? Suggestions include:
- Improved design for more accurate parameter recognition and human factors
- More research on alarm origins and causes as well as proper alarm settings for various patient groups
- Facility-wide policy initiatives supported at the highest levels to ensure that alarms are consistently set (in terms of defaults, alarm thresholds, and audio volume) and that caregivers respond appropriately
- Improved facilities design to enhance alarm recognition
- Multiparameter monitoring that integrates related physiological alarms into “smart” alarm systems
- Integrated alarm systems that collect data from disparate devices and present that data more effectively, perhaps on dashboard-like displays
- Better methods to train staff on alarms technologies and procedures
- Distributed alarm systems that transmit the right notifications to the right caregivers in the right way
- Better international standards on alarm systems that address distinctive alarm sounds and user interfaces
- Consideration of alarms issues unique to the home health environment

These topics and more will be considered at the fall Medical Device Alarms Summit, set for October 4-5, 2011 in Herndon, VA. Visit www.aami.org/alarms for details.

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Alarm safety, one of healthcare’s most high-profile and intractable problems, will be the focus of a fall summit being convened by AAMI, the American College of Clinical Engineering (ACCE), and the ECRI Institute. The summit aims to achieve broad consensus on the problem and identify specific actions to improve patient safety and ease demands on caregivers.

Nearly a decade after The Joint Commission first issued a Sentinel Event Alert on clinical alarms, alarm safety remains at the top of most lists of device problems. Many would say that the problem has only gotten worse.

“There has been a significant increase in the use of medical devices with clinical alarms over the past several years,” says the ECRI Institute’s Jim Keller. “The amount of noise and confusion generated by these devices has combined to make alarm fatigue a serious problem in clinical care.”

The Alarms Summit—which will take place Oct. 4-5, 2011 in Herndon, VA—is coming together in the wake of heightened concern over alarm safety. A recent survey by AAMI found that managing alarms is one of the top medical device challenges facing clinical engineering departments, and the ECRI Institute has named clinical alarms a top 10 technology hazard several years in a row. ACCE’s Healthcare Technology Foundation published a white paper on the topic in 2006.

“Our exploration of alarms as a potential topic for a 2011 summit actually gelled at the infusion device summit last October,” says AAMI’s Mary Logan. “Lela Holden’s keynote address there caught everyone’s attention because she shared in such a meaningful way her own experience with an alarm tragedy at Massachusetts General Hospital. Alarms kept coming up as one of the major themes at that summit. It became clear that this was a major ‘horizontal’ issue cutting across many devices.”

 Mario Castaneda, ACCE

The focus of the conference will be on identifying concrete steps that can be taken to improve the safety and effectiveness of clinical alarms. “There are many opportunities to improve the functionality of alarms,” says ACCE’s Mario Castaneda. “But no one can solve this problem by themselves. The complexity of the technology makes it impossible for one organization to address the issues. It will require collaboration.”

“AAMI, ACCE, and the ECRI Institute have been alarm safety thought leaders for many years,” says Keller. “The combined expertise of our organizations and members can be a powerful force to pave the way for real improvement.”

The summit is being modeled on the fall 2010 AAMI-FDA Infusion Device Summit, which led to a special publication mapping out key themes and issues surrounding infusion device safety. It also led to the establishment of the Medical Device Safety Council (www.aami.org/foundation/mdsc), which aims to tackle openly the sensitive issues of medical device safety in pursuit of zero tolerance for injury to patients. The council will likely play a key role in pursuing the action items that come out of this alarms summit.

The summit will include as many diverse stakeholders as possible. “We hope to bring the right people to the table so the entire community can identify the major issues, set priorities, and commit to work together toward solutions,” says Logan.
When an 89-year-old man died in his bed at Massachusetts General Hospital and the alarms that should have sounded didn’t, the incident set off a different kind of alarm throughout the hospital, in Boston, and in state regulatory agencies. The tragic situation also provided a learning experience for Mass General and the larger medical community. In that spirit, AAMI recently gathered a group of experts to discuss a number of alarm safety questions. What kinds of alarms are necessary, and how many alarms are too many? How can technology help solve this problem rather than compound it?

Mary Logan

What are some common problems seen with alarm systems for medical devices?

Linda Talley
I’m responsible for looking at how nurses interact with technology. The literature tells us, and our own experience at Children’s National Medical Center indicates, that we’re dealing with anywhere from an 85% to 99% false positive rate on alarms. We are inundated with information and alarms, most of which are meaningless to us.

Nurses become desensitized to the huge number of alarms they’re confronted with in their daily work and, as a result, critical or clinically significant events can be missed. We had a serious patient event many years ago that related to the timeliness of our response to a monitor. In our post-event review, we learned that it wasn’t an equipment failure. Rather, it was a human factors failure. That really prompted us as an organization to try to wrap our hands around the whole issue of alarm fatigue. We just completed a study funded by one of our alarm manufacturing vendors on the issue of alarm fatigue. We were aiming to partner with this vendor to increase the specificity and positive predictive value of the information the monitors give us.

Steve Wilcox
But I see two other problems with alarm systems. Besides the false alarms, the second problem is the lack of integration between devices. All these independently developed alarm systems don’t talk to each other or integrate in any way. So even if the false alarm problem was eliminated, there would still be this cacophony because of that lack of integration. The third problem is that the signals themselves are poorly designed so they’re not natural sounds. They’re difficult to learn and identify, and they go out of their way to be annoying. I think it’s an artifact of the way they’re designed.

Tobey Clark
IEC standards for alarm systems aim to prescribe a way to standardize alarms in terms of priority and parameters so people can learn and understand alarm signals, and better recognize the higher versus lower priority alarms. The American College of Clinical Engineering’s Healthcare Technology Foundation published a white paper about clinical alarms and one of their recommendations was for clinical alarm standards.
Talley  Of course these standards have made things a little more rational. But they haven’t addressed the problems of integration or false alarms.

Wilcox  Our experience, and our discussions over a three-year period with a vendor we were working with, indicates that device manufacturers are challenged as well by a consumer base that has asked them, over the past 10 years, to throw it all at us. We ask them to give us everything they can with these “magic machines” and we’ll deal at the front line with how we are going to discriminate between the massive amounts of noise we’re confronted with.

So I think they are very anxious to partner with us to figure out how to strike that balance. The machines we put in the hands of clinicians present serious challenges. The level of decision support is increasingly sophisticated and complex for any one clinician to manage. In many of our intensive care units (ICUs), we have additional personnel doing the decision support, trying to counteract the massive amounts of noise the technology produces.

In our study we recorded tens of thousands of alarms in a 30-day period, which translated to approximately 900 per day. In one of our critical care units, a total of 39,000 alarms were recorded in a 30-day period which equaled 1300 alarms per day, or one alarm sounding every 66 seconds. In another critical care unit, we observed approximately 600 alarms per patient per day.

In direct response to the sentinel event we had here at Children’s National several years ago, we decided every patient in every unit was going to be on a monitor. So we became even more acutely aware then of the dilemma of having very little science to drive how we are going to discriminate between alarms. What’s the primary purpose of them, rather than a visual phenomena. They set alarms to a lower threshold for surveillance, that is, letting you know when a patient needs to be rescued versus letting you know when a patient crosses the threshold. That is a very different approach to the traditional conditional settings found in ICU settings. By adding a delay to it, they were able to achieve four alarms per patient per day. And because of that, they were able to actually improve patient safety methods as measured by escalation of care to the ICU and rapid response activations.

On the technical side, monitoring companies have followed this paradigm of alarms being activated by the crossing of a threshold. Those thresholds often have not been defined using an evidence-based, rationalized approach to alert a nurse or clinician to go to the bedside.

In a study out of Johns Hopkins, they found that by lowering an SpO2 alarm from 90% to 88%, they were able to reduce the occurrence of alarms by more than 50%. A methodology to rationalize what’s an appropriate alarm is needed. The whole topic of alarm fatigue really begs the question of why are we doing alarms? What’s the primary purpose of them, and how do we create decision systems or filters so that nurses can focus on clinically actionable alarms?

Jim Welch  A study published in Anesthesiology focused on a general care setting, Dartmouth Hitchcock Medical Center, where my company worked directly with the end users. Rather than study how many alarms were occurring, we asked, “How many alarms are tolerable from a human factors standpoint to avoid alarm fatigue?” The nurses told us two to four alarms per patient per day.

I would encourage the community to agree to a common set of metrics and terminologies. Everybody knows what alarm fatigue is, but it needs to be defined. They took a different approach at Dartmouth by actually separating the alarm annunciation, or the sound of the alarm, because alarm fatigue is mostly an audio rather than a visual phenomena. They set alarms to a lower threshold for surveillance, that is, letting you know when a patient needs to be rescued versus letting you know when a patient crosses the threshold. That is a very different approach to the traditional conditional settings found in ICU settings. By adding a delay to it, they were able to achieve four alarms per patient per day. And because of that, they were able to actually improve patient safety methods as measured by escalation of care to the ICU and rapid response activations.

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Logan  What are the biggest obstacles to solving challenges related to alarms?

Wilcox  One is a strong bias toward false positives instead of false negatives. If an alarm signal fails to annunciate when there is...
Spotlight on Medical Alarms in Home Healthcare

What happens if a medical alarm sounds in a home, and the patient or caregiver doesn't know what to do? What if a patient and their caregiver are visually or hearing impaired? These are among the many issues to consider when placing medical devices with alarms into the home environment.

“Many patients already have a lot of anxiety regarding their illness, and placing medical equipment into their homes could add to this stress,” says Emily Seto, a manager and biomedical engineer for the Centre for Global Health Innovation, University Health Network in Toronto, Canada. “If false or unnecessary alarms are sent, then patients could lose confidence in using the medical equipment or suffer extra anxiety.”

Finding the right balance between maximizing safety and minimizing undue patient anxiety can become complicated. It takes good planning from not only clinical professionals but also manufacturers who must take into account new challenges when designing alarms for home devices. The issue of medical alarms in the home environment is especially critical because of the changing nature of healthcare with more patients being treated at home. In fact, home healthcare is one of the fastest growing markets in the healthcare industry.

One problem is how to respond to an alarm. “Should the patient go to the emergency department or call 911?” Seto asks. “It’s sometimes difficult to determine a protocol that patients should follow, and then to train or educate the patient on this protocol.”

Also, should healthcare providers be alerted when a home alarm goes off? “This brings its own challenges because the healthcare system is usually not prepared for such alarms,” Seto says. “It is often difficult to even determine who should respond to these alarms, especially if the alarms could be generated 24 hours a day.”

Another challenge is the alarm itself. Most of the people who are using home devices are the patient themselves. These patients could be confused, visually impaired, or hard of hearing. “Standard audio and visual alarms may not be heard and seen by those with hearing and visual impairments,” says Frank Block Jr., a retired anesthesiologist who is active in standards work related to medical alarms.

The patient’s caregiver, who in many cases is a spouse or family member, could be equally impaired or unavailable to hear the alarm. “Caregivers may be in another room in a house or apartment,” Block says. “Or there may not be a caregiver on the premises. If the alarm sounds, who will hear it?”

Block adds that another challenge is many devices have different controls, displays, and especially alarms. The various interfaces and combined noises from these devices can be overwhelming.

Finding Solutions
Manufacturers can help to solve some of the problems with alarms in home health devices, starting at the device design process, Seto says. Gathering input from the clinicians and patients during the design process is key.

Standardizing the user interface across numerous device types is another goal that manufacturers should look to, Block says. Home healthcare equipment should at least be re-designed to address patients or caregivers who are hearing or visually impaired, he adds.

The experts recommend that every hospital create protocols on how to respond to home-generated alarms, and these protocols should be developed prior to placing a device in the home. The alarm could alert “first responders over existing emergency networks and through a device that most individuals have in their homes: the telephone,” says John Zaleski, chief technology officer at Nuvon, software and hardware firm, in San Francisco, CA. Video and audio remote monitoring could also help clinicians and nurses determine the extent of the alarm and the condition of the patient, he says.

In the end, whatever solutions are implemented should help to ease the stress on the patient, Seto says, not compound it.
a legitimate situation, the liability is obvious. On the other hand, when the alarm signal annunciates when there’s not actually a problem, there is a logical liability because it’s undermining the value of the alarm. However, I’ve never heard of anybody being sued for a false positive. So to avoid even the thought of a false negative, we’re just inundated with false positives.

**Welch** There is a lack of research in this area. I’ve scoured the literature for publications on alarm recurrences, origins, and causes, and I’m only aware of a few published studies: the ones I’ve already mentioned and another in the *Journal of Emergency Medicine (JEM)*

The *JEM* piece studied the occurrence of alarms and what were clinically actionable events. It was predominantly focused on electrocardiogram (ECG) alarms, which is, I think, the primary cause of most alarms, along with impedance respiration rate. In the emergency room, they found that less than 2% of all alarms require a physician to do something at bedside to reverse the condition.

So what we don’t answer in the literature is, what’s being monitored? What’s the alarm mean? And what’s the profile of that alarm? We conducted a study in 10 hospitals looking at SpO₂ alarm occurrences using our technology. We found that if you set your SpO₂ alarm at 90%, you will have a lot of true alarms. But those true alarms do not require a clinical intervention. By lowering the alarm level from 90% to 88% and putting a 15-second audio delay on it, essentially a filter, we found that we could eliminate more than 80% of the alarms. So now we’ve got the alarms people care about, the ones where levels fall and stay below a threshold for a sustained amount of time, that would cause a clinician to rationally say, “I’m worried about that patient.”

**In part, machines are going off because they are too sensitive. With the probes we use in the home setting, if the client moves a bit too much or even if their extremities are cold, we see a lot of false alarms.**

**Angela Andrew-Webb** I can offer a home healthcare perspective on the alarm fatigue issue. In part, machines are going off because they are too sensitive. With the probes we use in the home setting, if the client moves a bit too much or even if their extremities are cold, we see a lot of false alarms. If ventilators are not set up properly, we can have water in the lines, which will give us false alarms also.

The payer source is our major obstacle to solving these problems. For instance, with ventilators, some of the home medical equipment (HME) companies are only compensated to give us two vent circuits a month. That means the circuits are only changed every two weeks. They need to be changed every week to function properly.
If we look at this from a systems perspective, think about links in a chain. If you don’t have the correct or optimized sensor, then you don’t have a high-performance sensor, and you’re going to generate false data. False data leads to false alarms. If you’re trying to use the same cable over and over and it’s at the end of its life and its signal is becoming intermittent, you’ll get false alarms.

So from a provider medical community, how do you optimize every link in that signal chain? Because the more you measure, the more alarms you’re going to have. Once you have optimized the sensor, its placement, the skin prep, and you’ve got a good signal, now you can ask, what is a rational approach towards where I set the alarms? For example, the heart rate area—is it okay to set it at 140 versus 120? If you do that, you will get fewer alarms. The question is, at what point is the alarm threshold set beyond a reasonable level, such that you’re causing harm? That evidence does not exist right now. And it’s not a one-size-fits-all solution.

The aircraft cockpit used to be like our situation in the ICU or the operating room (OR) today. Separate vendors made different devices that had alarms, and when multiple things started happening simultaneously, pilots were overwhelmed. But they had the advantage of a general contractor who could create a unified, integrated system that represents an alarm philosophy that is consistent.9 We’re not in that situation because there’s no comparable general contractor who can rationalize everything like in the aircraft industry. And there’s no incentive for individual manufacturers. So the only way that could happen is for hospitals and medical facilities to demand it. There have been third-party attempts to come up with a unified system that you plug all your devices into. To my knowledge, none of them have gotten off the ground yet, but ultimately that’s going to be one of the solutions.
Logan  **What steps can and should healthcare facilities be taking to address the problems?**

Hedley-Whyte  Solving this issue will require involvement from top hospital executives. These hospital executives are generally not aware of the problems we’re discussing today. The need for intelligent, integrated alarm systems generally comes as a surprise to them.

Clark  Individual hospital units typically follow specific policies for alarm parameters, which is appropriate. But at the institutional level, there isn’t a clear awareness of the problem. Unfortunately, the reporting of alarm events in *The New York Times* or *Boston Globe* that are read by a trustee or hospital executive is a common impetus to develop an alarms improvement program.

Wilcox  Facilities can use the likelihood of false alarms as one of the top criteria for acquiring devices. Right now, that criterion is pretty low on the list, if it’s even considered at all when comparing devices. However, with the lack of good metrics or research that compares one vendor to another in a lot of parameters, it is very difficult for healthcare organizations to make those decisions. Some organizations like ECRI are beginning to test various technologies relative to false or nuisance alarms.

Hedley-Whyte  When I am asked to visit other medical institutions, I have found it rare that hospitals have appropriate alarm policies. To initiate rational alarm policy often takes a committee or a very powerful central administration. The development of rationalized policies and procedures should be based on local evidence and published literature.

Also, the move of so much medicine and surgery toward home care does require urgent rethinking of the alarm systems that should be deployed. Nobody on a ventilator, hemodialysis machine, or infusion pump at home should be left without a distributed alarm system. It is nonsense to think that a single alarm is sufficient. You need a system distributed to other rooms where other people are.

Cartwright  From a home healthcare perspective, it's part of our assessment to verify
that an alarm can be heard in every area of a home. Desensitization to alarm sounds is also a problem in the home environment. Because there is not a clinical person there with the patient all the time, family members come up with their own interpretation as to what alarms mean because of what has happened in the past. Often, family members will actually turn off alarms because they’ve heard so many false ones.

Welch In fact, if you go through device incidents reports, you’ll find that home apnea monitors are one of the most egregious examples of too many false or nuisance alarms, and an inability to relay the true alarms that somebody would do something about. Remote annunciation of alarms is essential because caregivers, especially ones outside ICU settings, are not at the bedside when these events occur.

However, if you don’t solve the problems of nuisance alarms or alarm fatigue, moving those alarms to an already-busy clinician, home healthcare provider, or family member is just going to annoy them, and they’re going to turn off alarms. So first solve the alarm fatigue problem, and then start thinking about how to get alarms to the right person to rescue that patient.

Logan What should industry be doing to address these problems?

Hedley-Whyte There are many barriers to what industry can do to solve these problems in the home environment. In Massachusetts, we’ve had political infighting to get sophisticated, distributed alarm systems deployed in the home. You have to battle insurance companies for reimbursement to wire another room, set up a local area network, and so forth.

Welch Until there’s reimbursement for companies developing these body-worn sensors for home healthcare, you are not going to get venture capitalists or their companies to invest because there’s no profit in it. On the acute-care and the long-term care side, however, industry definitely can do more because that’s where monitors are today. How we solve these problems is really the call to arms.

At a children’s hospital, we analyzed what measurements are most often alarming. We found that respiration rate was the root cause of most of the alarms that were driving nurses, patients, and families crazy. So that gives us an attack point from a technology standpoint. What can we do about improving that particular parameter? How do we integrate all of the parameters? For instance, why not couple respiration rate with oxygenation in patients? There are some rational ways of approaching this. The question for industry is, will that provide a competitive advantage of one company versus the other?

Logan AAMI has just established a new standards committee on alarms, because of the importance of the issues that need to be addressed from a standards perspective. What do you think is needed on the regulatory, accreditation, or standards fronts to deal with this issue?

Hedley-Whyte The international standards-setting process in this area is not smooth at all. We’ve had international standards for about 40 years on alarm systems. There’s currently a disagreement between two standards bodies on how to approach these systems, which needs to be resolved.

Logan The new AAMI standards committee is waiting to get started until they hear the needs and priorities from all perspectives at the alarms summit that AAMI is co-hosting this October 4-5 with ECRI Institute and ACCE. The committee is also waiting on a revision of an updated IEC foundational standard (60601-1-8), upon which our new work will build. If we can solve many of the challenges with alarms from what we learn at this year’s summit, then hopefully this preferable non-regulatory route for improvements throughout the system will eliminate the need for any additional regulatory action.

In 2002, the Joint Commission issued an alert on alarm safety. . . We’re almost 10 years past their recommendation and we’ve made little to no real advance in solving this alarm safety problem.
Talley  In 2002, the Joint Commission issued an alert on alarm safety. That was helpful; it established a call to action and gave us leverage to say we are all accountable. We’re almost 10 years past their recommendation and we’ve made little to no real advance in solving this alarm safety problem. The Joint Commission has since established a standard aimed at appropriate alarm settings and audible alarms. It’s a start; however, it does not effectively get us to where we need to be. Clinicians are still encountering alarm fatigue in the hospital setting.

Logan  What next steps are needed to solve these problems?

Talley  We must continue to seek research opportunities. Healthcare providers must represent the patient and the family interests. As we said earlier, vendors are looking at the bottom line. The providers are the ones who are most closely aligned with patient/family interests. And it is incumbent on us to keep the topic alive through research endeavors. The more we can look at it from an evidence-based perspective, the more we can maintain the momentum we’ve begun here.

Welch  This is an enormously important issue in healthcare because we’re already seeing that, due to so many nuisance alarms occurring, hospitals are looking at not monitoring patients. Removing the technology because there are problems with it is a step backward. Therefore, at a stakeholder meeting, it’s going to be extremely important to have the right participants representing the political, financial, insurance, and vendor spectrums. Everybody recognizes that this is a worthy problem to solve. Getting agreement and collaboration on a way forward is the only way this is going to be solved.

Andrew-Webb  With home healthcare, we need to work more with vendors to make sure they’re aware of issues we are having with alarms so we can present that to insurance companies and try to resolve these issues together.

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An FDA Response on Alarm Systems Issues

Editor’s note: Horizons separately posed the same list of questions to a group of experts from the U.S. Food and Drug Administration (FDA). Their responses follow.

What are some common problems seen with alarm systems for medical devices?
Based on medical device reports we have received in the past several years, it is often difficult to assign a root cause to problems reported concerning device alarm systems. The most commonly reported alarm system issue is that the device does not provide a critical alarm. Often, the alarms are not heard or they have been silenced or deactivated and never reset. Sometimes the lack of an alarm is due to mistaken disconnections from a central station or inoperable speakers.

What are the biggest obstacles to solving challenges related to alarms on medical devices?
• The challenging environment in which these alarm systems are used:
  - A vast number of potential alarms competing for a caregiver’s attention in the typical hospital environment
  - Significant concurrent clinical demands on caregivers
  - Ensuring there is sufficient staffing to respond to all alarms
• Regulatory clearance to market typically applies to individual devices rather than entire systems—often for relatively minor modifications to devices that have been on the market for many years
• Lack of a systems approach to integrating alarms on devices from multiple vendors
• Differences between user interfaces related to alarms on various brands of systems
• Increasing complexity of monitor user interfaces
• Difficulty determining the optimum balance between sensitivity and specificity of alarms

What steps should healthcare facilities take to address problems with alarm systems?
FDA does not regulate healthcare facilities. However, we note that adverse event reports are very helpful to us in assessing problems with alarm systems and how to address them. We recommend that users and facilities submit adverse event reports that are as detailed as possible to the manufacturer and FDA regarding cases that involve alarm systems.

What steps should device designers and manufacturers be taking to address problems?
User interfaces for alarms should be as consistent as possible across vendors to minimize use errors. Alarm system user interfaces should be developed based on sound human factors principles and tested with representative end users to validate that the alarms are effective. Alarm design should take into account the other device alarms likely to be in the same environment. Intelligent alarm systems should be developed to improve the effectiveness and safety of alarm systems.

Standardization is most essential around the safety aspects of devices, of which alarm system design is a critical part. A consensus standard should be developed that describes appropriate approaches to the integration of alarms across vendors in a clinical setting. Manufacturers, healthcare providers, and regulators should work together in developing such a standard.

What efforts are needed or underway in the regulatory/standards front?
The FDA is looking closely at this problem to determine what role we can play in mitigating alarm-related hazards given that we do not regulate healthcare facilities where alarm system integration occurs. The FDA has recognized the following applicable standards and is promoting their use in pre-market submissions:
• IEC 60601-1-8
• AAMI/ANSI HE75:2009, Human factors engineering - Design of medical devices
• IEC 62366, Medical devices - Application of usability engineering to medical devices.
We are also looking to open a dialogue with relevant standards organizations, manufacturers, and care providers to explore potential options.

What are the implications of current trends for alarm systems?
FDA is actively tracking a number of emerging trends in healthcare monitoring, including more personalized monitoring and targeted alarms as well as trends related to wireless technologies, interoperability, and home healthcare. As alarm technologies advance and alarm systems continue to become more distributed and complex, it is important to assess how their functionality impacts patient care and healthcare provider work processes (human factors). Device alarm systems need to be designed appropriately for each intended use environment, use, and type of user.

What comes next?
FDA is working to identify what else can be done to address the issues discussed and to develop additional guidance related to these issues.
Why Clinical Alarms Are a ‘Top Ten’ Hazard

How You Can Help Reduce the Risk

James P. Keller, Rich Diefes, Kelly Graham, Mark Meyers and Kathy Pelczarski

Take a look around your hospital for medical devices and systems with alarms. You’ll find them on infusion pumps, physiologic monitors, ventilators, anesthesia machines, dialysis units, laparoscopic insufflators, and so on. It’s amazing how much the healthcare system has grown to rely on medical device alarms. It would be hard to walk into almost any type of patient room or care area and not find an alarm-based device being used. In critical care areas, it’s typical to find a dozen or more such devices, just for one patient. And these devices are now starting to become interconnected and are sharing lots of critical information, including alarm data.

With such widespread use of alarm-based medical devices, you’d think we would have a very effective safety net to warn about serious changes in patient conditions or performance-and safety-related problems with devices. Unfortunately, as many experts agree, there are serious problems with the design and use of device-based clinical alarms. Clinical alarms have been at or near the top of the ECRI Institute’s list of “Top 10 Health Technology Hazards” since the annual list was first published in 2007. It remains near the top because alarm-related events are all too common, and the consequence of these problems can be extremely serious.¹ ²

Alarm Fatigue and Confusion
In early 2010 The Boston Globe reported on a typical alarm-related problem in which a patient’s death may have been due to a critical physiologic monitoring alarm being turned off. That incident was attributed to alarm fatigue, in which caregivers can become overwhelmed by the sheer number of alarms.³ Alarm fatigue can cause caregivers to unsafely modify alarm settings or silence alarms in order to reduce alarm overload. Or, caregivers can become desensitized to alarms and miss or delay their response to critical patient events.⁴

When you do your look around the hospital, consider how many different types of medical device alarm settings are being used.⁵ Often, two different models of the same device type can have slightly different ways to set the same type of alarm. This can confuse caregivers who have to operate and adjust alarms for both models. ECRI Institute has investigated alarm-related incidents in which this type of confusion has had fatal consequences. The risk of this happening is magnified when you consider that many devices have multiple alarms, often with several different ways to adjust them.

Most medical devices with clinical alarms are intended for use on a variety of patients with a variety of medical conditions. As such, their alarm limits and other parameters are adjustable to meet the needs of the many types of

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patients that they will be used on. This level of flexibility can be helpful but is of no value and can even be dangerous if not used properly. For example, a pulse oximeter used in a neonatal intensive care unit should have different oxygen saturation limit settings than the same device used in an adult intensive care unit. Or, the pressure limit settings for a ventilator that is used on an adult vs. an infant must be adjusted to completely different levels. The acceptable limits for the adult patients will likely be lethal for the infant.

Unfortunately ECRI Institute has seen many examples of alarms not being set according to the appropriate care area or patient type. In some cases this is because hospitals have not established specific alarm setting protocols for their different types of clinical settings and patients. Or the hospitals have established protocols, but they were not followed or understood. We've also seen examples of two or more of the same model device being used to treat patients with similar clinical conditions in the same care area with completely different alarm settings.

**Efforts to Improve: An Overview**

The problems described have helped to focus attention on the need to improve the design of clinical alarms and how they are used. Medical device manufacturers are working hard to improve features. New products like alarm integration systems can help present alarm data from disparate devices and systems in a more organized and functional manner. Cell phones and other communication devices can now deliver critical alarm data to caregivers, thereby potentially increasing their responsiveness to critical changes in patient conditions. Some of these efforts are supported by the resources from various medical device-related standards organizations, most notably from the International Electrotechnical Commission (IEC). Its 60601-1-8 standard provides general requirements for alarm systems and is intended to be applied to all medical devices with alarms.6

Many healthcare organizations are taking a hard look at how clinical alarms are used and managed in their facilities. They typically find the need for significant improvement. Some have identified technology solutions like those described above. Others have chosen to focus on process changes utilizing their existing technologies, sometimes because of financial limitations. Others have implemented a combination of technology- and process-based changes.

The most successful efforts to improve alarm-related safety come about through systematic and critical analysis of how clinical alarms are used across all care areas in the institution. It requires strong commitment and a willingness to change at the highest levels of the organization. The analysis, improvement design, and implementation of an improvement plan must have active participation and buy-in from, at a minimum, clinical (including physicians), risk management, administrative, information technology, and clinical engineering staff.

Safe and effective management of clinical alarms is very complex. It’s impacted by the hospital’s mix of technologies, its care models, patient population, the physical layout of each care area, staffing patterns, staff education and training models, the hospital’s safety-related “cultural” mindset, budget, its history of alarm-related problems, and many other factors. Any new technology will typically bring some new unintended risks or problems. Any initiative to improve the safety and effectiveness of clinical alarms needs to carefully consider all of these factors. All of the parties involved need to come to the table with the understanding that this will involve lots of hard work and will likely result in significant change to existing workflow and processes.

**Step 1: A Safety Assessment**

The first step in any institution-wide alarm safety improvement project involves setting up a multidisciplinary team. This team should be responsible for understanding the hospital’s history of alarm-related events and near misses, how alarms are used throughout the institution, its existing clinical alarm-related policies and procedures, technology-related capabilities and limitations, actual practices, and probably most importantly, how clinical staff feels about alarm-related performance and response in the hospital.

The history of the hospital’s alarm-related events and near misses can be identified from the hospital’s incident reporting system, incident reports filed to manufacturers, FDA, insurance companies, and independent reporting organizations such as ECRI Institute. It can also come from review of alarm-related root cause analyses, results from clinical alarm problem remediation projects, and summaries of alarm trending data from physiologic monitors and other alarm-based medical devices. It’s likely that this review will identify problems in many if not all of the hospital’s care areas. Solving all alarm-related problems at once is probably an unrealistic task. This type of analysis can help hospitals identify where problems are most serious and can provide ideas on care areas or alarm problems to focus on first.

**New products like alarm integration systems can help present alarm data from disparate devices and systems in a more organized and functional manner.**

An assessment of alarm use should include mapping the processes for alarm notification and response, discussions with clinical staff about their alarm-related concerns, and observations of how alarms are set and used in different care areas. The assessment should keep an eye out for problems with alarm
Step 1: Problem Identification

The first step in any institution-wide alarm safety improvement project involves setting up a multidisciplinary team. Responsiveness or desensitization, difficulties with clinical staff’s ability to hear alarms, large numbers of nuisance alarms, the frustration level of clinical staff during alarm conditions, or general signs of trouble like alarm pagers not being worn.

Information from the historical analysis and assessment of alarm use can be used to identify key institution-wide alarm vulnerabilities and potential failures. Examples include alarm fatigue, apathy to alarms that are incorrectly perceived to be “low priority” such as leads-off, or breakdowns in transport communications. This may help point to problem causes such as diffuse responsibilities for alarm response, competing staff priorities, infrastructure limitation, inadequate training, a weak safety culture among clinical staff, or specific technology limitations. Once the problem causes have been identified, the committee can begin to develop its improvement plan. 7,8

Step 2: Improvement Planning

The interdisciplinary alarm improvement team should plan to develop realistic, implementable strategies to address underlying causes of the alarm problems it identified. The plan should start with strategies that apply to most hospitals. They may include:

- Establishing protocols for proper electrode skin preparation and placement
- Setting alarm limits to the specific patient population
- Tailoring alarm limits to the individual patient care area
- Elevating the response priorities for critical alarms like those identifying a leads-off condition

Strategies that require more in-depth process analysis include:

- Delineating responsibility for alarm response
- Developing plans for tiers of coverage
- Delineating responsibility for back-up response
- Implementing technology solutions such as two-way pagers for providing alarm notification directly to the caregivers
- Establishing policies for meeting alarm-specific safety criteria during the technology selection process

Whichever strategies are implemented, it is essential to provide staff education and training including why the strategy is important and how it should be implemented. Whichever specific plans are developed, a key goal is to have alarms that are actionable so that, as much as possible, staff are being alerted to only clinically significant alarms, thereby minimizing the risk of alarm fatigue. 9,10

Success Stories

ECRI Institute gives out an annual award called the Health Devices Achievement Award. It is designed to recognize technology-related initiatives that our member hospitals undertake to improve patient safety, improve overall healthcare quality, or reduce costs. Two of its award honorees (William Beaumont Hospital and Boston Medical Center) were recognized for projects that had significant impacts on improving alarm safety. The Johns Hopkins Hospital is another example of an organization that put serious effort into finding ways to improve how alarms are managed and used.

William Beaumont Hospital

William Beaumont Hospital in Detroit, MI undertook an alarm improvement project because of general complaints with the responsiveness of its clinical staff to critical alarms from a newly installed telemetry monitoring system.

Beaumont assigned a multidisciplinary team to further investigate the problem. It first decided to measure the time it took for clinical staff to respond to alarms. It was found that the mean response time was 9.5 minutes, which was clearly a dangerous situation. This led to a critical review of how alarms were being communicated by the telemetry system and the clinical staff on the telemetry ward. At that time, specially trained telemetry technicians were assigned to verify alarms and then page the patient’s nurse. The nurse would then call to confirm receipt of the page and to request any additional information. If the nurse did not respond within 3 minutes, the technician would reissue the page. If necessary, the page would be directed to other personnel following the specified “chain of command.” Unfortunately, pages were frequently missed and then had to be reissued, which led to the nurses becoming...
desensitized to the pages and contributed to the unacceptably long alarm response times. A detailed failure mode and effects analysis led to a solution to the problem based on implementation of a two-way, voice-activated wireless communication system. The system allowed telemetry monitoring technicians to speak directly to nurses through the communication device, and the nurses could speak directly to the technicians to ask questions. The new technology significantly streamlined Beaumont’s alarm notification protocol and drastically shortened alarm response times. Mean alarm response time dropped from 9.5 minutes to 39 seconds, well under a planned improvement target of 3 minutes. Also, use of the two-way communication devices led to a 100% closure of the communication loop, compared with an average of 35% before the project began.¹

**Boston Medical Center**

Boston Medical Center (BMC) had recently observed a wide disparity in how alarm limits were being set, particularly in its telemetry wards. It was also experiencing a large number of low-level alarms that contributed to the noise levels in these areas and probably alarm fatigue.

After careful analysis it implemented a program to standardize the alarm setting defaults in the telemetry wards. It also insti-

**The Johns Hopkins Hospital**

The Johns Hopkins Hospital in Baltimore, MD completed a study on overall alarm management in its Medical Progressive Care Unit. The medical step-down, which had a diverse patient population, commonly saw fluctuating vital signs with sudden changes in hemodynamic status. Its pre-implementation data revealed bradycardia, low heart rate, high heart rate, oxygen saturation and leads fail as their most common alarms.

The hospital’s interventions included a pre- and postnursing survey on alarm management and noise level, education on best practices, troubleshooting methods and customizing of parameters, and patient monitoring software enhancements that included a split screen view that allowed crisis alarms to sound at the central station as well as every bedside monitor. A hospital-wide Monitor Alarm Taskforce team was also started and involved the Medical Progressive Care Unit’s Comprehensive Unit-Based Safety Program.

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The Healthcare Technology Foundation, a 501c(3), was founded in 2002 on the principle that achieving improvement in the safe use of healthcare technology requires diverse stakeholders to come together and use their collective knowledge for the design, use, integration and servicing of healthcare technology, systems and devices.

The many issues surrounding the safe and effective use of alarms provide an excellent example of the need for such broad collaborations, and we are therefore enthusiastic in our support of this issue of *Horizons*.

Work of the HTF on Clinical Alarms Management and Integration can be found at [http://thehtf.org/clinical.asp](http://thehtf.org/clinical.asp)
(CUSP Team). This team helped revise alarm limit default parameters by analyzing the patient population to determine the best and safest settings for that particular unit. In making these adjustments the team focused on frequent, duplicate, and nuisance alarms. Data were collected approximately a year later and revealed a 43% decrease in critical alarms that led to a hospital-wide initiative for improving and standardizing alarm management.13

New Directions

New products like alarm integration systems can help present alarm data from disparate devices and systems in a more organized and functional manner. And cell phones and other communication devices can now help caregivers at facilities such as Beaumont Hospital improve their responsiveness to critical changes in patient conditions. So what will or should the next generation of clinical alarm technology improvements be like?

They should first address how the patient is doing from a holistic point-of-view. Most of today’s monitors or other alarm-based medical devices have one or more discrete alarms that trigger when a specific limit is reached. They don’t consider for example how pulse rate, ECG heart rate, and oxygen saturation relate to one another. The next-generation alarm systems will need to serve as smart or intelligent monitors that integrate a variety of patient parameters and warn of serious changes to a patient’s overall condition. In some cases one of these “collective” alarms will sound earlier than on today’s discrete devices (e.g., because several physiologic parameters are trending together in a negative direction). In other cases, the number of nuisance alarms will decrease because “outlier” conditions will be classified as being not clinically significant. The new system will be smart enough to not sound for the outlier condition because other physiologic parameters will be trending just fine.

Two-way communication devices like the one used at William Beaumont will evolve so that all pertinent alarm information is presented in a clear and organized way, eventually in a heads-up display. The alarm data will include information on the patient’s current location, possibly a video feed of the actual patient, and appropriate trending information that holistically shows how the patient is doing based on a range of physiologic parameters.

On a shorter term improvement timeline, medical device manufacturers should design their alarm features so that their limits cannot be adjusted to clinically unsafe levels. Their alarms off or silence features should not allow for conditions where patients are not being fully monitored for minutes at a time. When alarms have been defeated or silenced, devices need to provide a very clear indication that they are in a disabled state. And, as alarm data is transmitted from one device to another (e.g., via wireless networks) safeguards will need to be put in place to make sure that the information is transmitted accurately, and without interruption or delay.

Conclusion

Clinical alarms are a serious problem. About a year after its initial story on alarms, The Boston Globe reported in February 2011 on more than 200 alarm-related patient deaths from January 2005 through the middle of 2010.14,15 Considering the underreporting of medical device incidents, the number is likely much higher. A survey during a recent ECRI Institute webinar on clinical alarms found that almost 75% of its listening audience had experienced at least one serious alarm incident in the two years prior to the program.16 Many hospitals have taken notice and have undertaken significant efforts to improve alarm safety. Some have identified technology-focused solutions and others implemented clinical process changes or a combination of both.

Hospitals that still need significant improvement should conduct a comprehensive assessment of the state of their alarm-based technologies and processes. Regardless of the solutions identified, nothing will work without full participation and cooperation of clinical users. And the clinical users need full support from their hospitals’ leaders. One of the most important ways to provide that support is to make sure that all users fully understand the hospital’s clinical alarm protocols and how to use and respond to the alarm features of all alarm-based medical devices. Clinical and biomedical engineering professionals should play an important role in making sure this happens and ideally should be the lead or major contributor to any healthcare organization’s alarm improvement initiatives. ■
### STRATEGIES TO IMPROVE MONITOR ALARM SAFETY

#### Alarm Management is Complex

**Improve the effectiveness and efficiency of alarm management!**

1. **Assemble a multidisciplinary team**
   - Administrative sponsor (e.g., CNO, VP Quality)
   - Key medical staff
   - Nurse managers
   - Front-line nurses
   - Monitor technicians
   - Patient safety/risk manager
   - Clinical engineering staff
   - IT staff
   - Consult with others, as appropriate

2. **Review recent events and near misses**
   - Root causes
   - Frequency of alarm types
   - Aggregate of alarm types per care area/shift
   - Review remediation/results
   - Trends
   - Identify obvious problems
   - Excessive alarms
   - Difficulty in hearing alarms
   - Delayed alarm response
   - Pagers not being worn

3. **Observe alarm coverage processes and ask nurses and other staff about their concerns**
   - Routine rounding
   - Listen to staff concerns/problems
   - Map processes for alarm notification and response
   - Identify obvious problems
   - Follow-up, Excessive alarms
   - Difficulty in hearing alarms
   - Delayed alarm response
   - Pagers not being worn

4. **Review entire alarm coverage system**
   - Culture
   - Infrastructure
   - Practices
   - Technology

5. **Identify patient safety vulnerabilities and potential failures**
   - FAILURES
     - Delayed alarm response
     - Transport Communication Breakdown
     - Leads-off Apathy
     - Alarm Fatigue
   - CAUSES
     - Diffuse responsibility for alarm response
     - Competing priorities
     - Assumptions that someone else will respond
     - Excessive nuisance alarms
   - THINGS TO CONSIDER
     - Diffuse responsibility for alarm response
     - Competing priorities
     - Assumptions that someone else will respond
     - Excessive nuisance alarms

6. **Develop realistic, implementable strategies to address underlying causes**
   - TODAY FIXES
     - Proper skin prep
     - Proper electrode placement
     - Routine change of electrodes
     - Battery replacement every 24 hours
     - Elevate “Leads-Off Alarms” to crisis priority

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Figure 1. Strategies to Improve Monitor Alarm Safety. ©2011 ECRI Institute. Reprinted with permission.

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### References


“If you build it, he will come.” (Field of Dreams, 1989). Certainly, this is what hospitals envision when creating clinical simulation centers to help train staff on a variety of procedures and processes. There is tremendous value in these centers, but part of the challenge is outfitting them with the technology that staff use in the care of patients. In addition, getting staff to these centers can be problematic, since they are often not close to inpatient areas.

Such simulation labs are valuable in training staff on such items as changing alarm parameters. Managing alarms is a daunting task, given the number of devices and the varied tones and alerts of devices used in a typical clinical setting. Competing alarms present an aural challenge to staff, and erroneous alarms add greatly to noise pollution on the unit.

To reduce nuisance alarms and fine-tune alarm parameters and defaults so that true alarms are presented, the clinical engineering department at Boston Medical Center (BMC) took on the standardization of telemetry alarms and portable monitor alarms. As we investigated, reviewed, and discussed alarms, we found that adjusting parameter defaults was essential in managing patients on telemetry devices. With the introduction of standardized defaults and alerts across care areas, the issue of educating staff about the changes presented a challenge. Many of the changes were subtle and did not translate well through emails, posters, or other non-auditory means. And, as mentioned, getting staff to simulation centers presents challenges.

This article describes how the clinical engineering and nursing education departments at BMC took on the task of creating a portable, self-contained telemetry system to educate staff about changes in telemetry alarms and portable monitor alarms. The system enabled us to demonstrate current alarms (both visually and audibly), and show staff the changes. This system greatly enhanced the educational experience.

Telemetry Growth and Challenges
The use of telemetry afforded BMC more bed space, providing monitoring of patients without under-utilizing critical care beds. With sicker patients came the need to rapidly deploy additional telemetry capacity, and with this came increased challenges in staff training, the variety of areas (surgical versus medical),
and differing views on unit standards. Also, the increased number of monitored beds exposed us to the potential for more events and near misses.

It was apparent that addressing these challenges, coupled with undefined device standards, required a team-based approach. A joint effort was undertaken by the chief medical officer, several key physicians, nursing educators, nurse managers, and clinical engineers to provide a stable basis for setting alarm expectations so that consistent specificity of alarms could be achieved.

Improvement Initiative
Nursing and Cardiology established new telemetry standards to better define candidates for telemetry, the duration for use, and what to do with patients who leave the floor while on telemetry. The process for managing the telemetry patient required enhanced systems review, addressing education of both the nursing and house officer staff, tempered by the limitations of the telemetry system.

Despite many technical advances, alarms frequently go off, mostly due to rate violations, artifact, or insignificant arrhythmias. The fine-tuning of an alarm system is limited, and the ability to specifically detect and alarm only significant arrhythmias is currently an unattainable goal. To further exacerbate this problem, training a large number of staff is difficult in a classroom setting. Arrhythmia detection is challenging, and filtering through the very large number of alarms on a busy unit is extremely difficult.

One particular challenge physicians face is fine-tuning parameters for individual patients, rather than using default settings. A review of system capabilities showed that our current system could be modified in a clinically useful way, but that the system was not widely used. This collaborative approach proved to have some tangible benefits through the transfer of knowledge, the increased utility of the telemetry system, and the creation of focused discussions between physicians, nurses, and engineers.

Taking into account what was identified, the committee agreed to shift priorities to address the following short- and long-term priorities to improve telemetry utilization:
• Nurse orientation and education
• Attending and house officer education
• Order sets to optimize settings for individuals
• Review of alarm settings, clearing of inappropriate/erroneous alarms
• Improved training

The committee undertook a concerted effort to address issues with education, utilization, and alarm management. One of the first actions was to review the vast list of parameter alarm defaults, and create consistent definitions of alarms and the associated warnings across the 12 telemetry areas. The monitoring system we use has 16 arrhythmia alarm levels and three levels of associated warnings. Creating a unified list to be formatted across the campus was an important first step.

The next aspect of the changes included the creation of standardized premature ventricular contraction (PVC) thresholds as well as high and low heart rate (HR) limits. Both electrocardiogram [ECG] and pulse oximetry

Nursing and Cardiology established new telemetry standards to better define candidates for telemetry, the duration for use, and what to do with patients who leave the floor while on telemetry.
This first phase of standards was intended to ensure that all units categorize arrhythmias consistently, reducing the quantity of low acuity, low HR limit violations and alarms for PVC counts. Computerized physician order entry (CPOE) systems offer a great benefit because rules and stops can be integrated into the system across the enterprise, which can help normalize practices. Nursing and Cardiology, after reviewing the policies and investigating other institutions’ practices, engaged the help of the information technology analysts who manage the CPOE to create an enhanced order set for telemetry. Now, all attending physicians and house officers are using a more robust and defined order set that addresses utilization and parameter defaults with the intent of improving communication about telemetry patients and promoting discussion between the nursing staff and physicians. Moreover, the appropriateness of utilization was included to better define candidates for telemetry and to provide reminders about the duration of the orders.

Another benefit of the multidisciplinary group was to have subject matter experts available to discuss issues and arrive at strategies to transfer the information to all parties associated with the efforts. With more defined alarm parameters and order sets, a reduction of low-level and nuisance alarms was noticed, but the issue of other parameter alarms and the filling of alarm histories required review and cleaning up so that the true alarms were part of the patient’s data. Cardiology worked with Nursing to review the process and to identify the best way to manage these per patient. From this, an action list of alarms and issues was identified to be reviewed by the committee as needed.

Another benefit of this group was the recommendation and creation of a full-scale telemetry training course that was ultimately provided to more than 700 nurses on medical-surgical floors with telemetry. The online course covered orientation, education about telemetry policies, and arrhythmia detection/interpretation. The test requires a 100% score and annual accreditation is expected. Additional aspects of the training included crisis alarm protocols to notify physicians, alarm review, and the creation of a simulation area where staff can go through the process of admitting a patient to the telemetry system. On the physician side, we have instituted an orientation program on the telemetry system for incoming interns that includes:

- How to do telemetry review—both checking events and graphic trends
- How to open from events or graphic trends to full disclosure to see more detail
- How to print alarms and full disclosure
- How to remove alarms from history
- What alarms sound like, from Advisory to Crisis
- Accountability when silencing alarms

To solve these problems, clinical engineering, in partnership with the nursing education staff, designed and built a portable, self-contained telemetry system that can be rolled around campus to demonstrate the different changes in alarms, and allow staff to interact with the system without involving live patients.

These strategies for orientation, order sets, and default standards proved to be beneficial in 2009 as we added nearly 100 beds of telemetry capacity to the institution in just two months. Having a defined education and systems process made the expansion progress much more efficient and safe, as many previous issues were identified and built into the program standards. The clinical staff was oriented to the telemetry process and the technology prior to installation, which made for a better transition into clinical use.

**Portable Training System**

The orientation process for cardiac competence was an obvious focal point for improvement efforts. Unfortunately, it became difficult to share the system overview with staff due to the configuration of the simulation lab, as well as the limited times available to provide this training.

In the simulation center, we found it difficult to teach staff about changes in alarms due to the lack of technology dedicated to telemetry. However, it was also difficult to relay this
information in the unit, because many of the default changes were time-consuming, and created a disruption there.

To solve these problems, clinical engineering, in partnership with the nursing education staff, designed and built a portable, self-contained telemetry system that can be rolled around campus to demonstrate the different changes in alarms, and allow staff to interact with the system without involving live patients.

**Design criteria**

As we began to develop the system, several key design criteria became apparent. For it to be most effective, we had to ensure it would meet not only the functional requirements for training, but also the ergonomic requirements of educators, so they would use the system. We identified several criteria for the system, and built it utilizing existing monitoring hardware and some “found” items. The following were paramount:

- The system had to exactly create the experience of managing a patient on telemetry, including admission/discharge process;

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**alarm events are accidents waiting to happen—the result of a perfect storm in an error-prone system. Patient deaths and other alarm-related events plague hospitals and make the news. And, they persist on ECRI Institute’s annual list of Top 10 Health Technology Hazards.**

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alarm setting; alarm annunciation; event review; and storage of patient data.
• The system had to withstand rolling across a large, urban campus with the following issues addressed: size and weight of the system; stability; portability; security of devices during transportation—mounting limitations and requirements; adequate storage to contain all components necessary to operate, including batteries and simulators; cables and leads; operating manuals and educational materials.
• The system had to be easy to set up, so that users could move it from area to area without a great deal of effort.
• A detailed power on-off instruction sheet was developed to ensure the system would operate as required.

The cart (Figures 1 and 2) is comprised of a telemetry server, receiver cabinet, patient monitor, central station, network switch, antenna system, display, keyboard, and mouse and simulators.

Introduction of the training cart
The use of the cart came into play in fall 2010 during a two-day educational blitz we set up with our patient monitoring system vendor partner. The goal of the education program was to provide an on-site educator from the monitoring company to answer user questions, handle orientation of new staff, and work with our educators to enhance their understanding of the system capabilities. We wanted the educator to visit each of the care areas so he or she could answer questions on the fly, see what the use models looked like, and afford more users access to this resource, since they would not have to leave the floor.

The cart accompanied the team (vendor educator and nurse educators) so they could see what changes had occurred to the system, and could transfer knowledge using the actual system. We found this to be a truly effective method of orienting staff, and it provided a real-time method of system utilization.

Examples of use
As we continue to assess and make changes to device and alarm defaults in an effort to ensure maximum patient safety, the cart has proven to be invaluable in demonstrating what current defaults entail and what changes will result. This approach provides a way to demonstrate the cause and effect of these changes, and enhances any written or course material that may accompany the changes.

Recently, we recommended a change in one of the network alert alarms. We were able to demonstrate this to the Code Committee and Nursing Executive Committee by showing the current alarm, what the new alarm would look and sound like, and the benefits of the change. It proved to be an effective way to transfer knowledge in a real-time environment. The changes were evident, and prompted good discussion. We foresee that this will be a good system to test changes as they arise, and then demonstrate to users what they entail and what the end result will be.

Summary
The cart, while relatively new, has proven to be an extremely effective means to demonstrate the capabilities of the telemetry system. It allows clinical users a hands-on, real-time means of reviewing the system and changes in use. User feedback has prompted us to make minor modifications in a couple of areas including securing the bottom drawers so they do not open during transport and changing the height of the central station display so it does not compete with the patient monitor display. The cart has proven to be a valuable teaching and system utilization tool. It has also bolstered the partnership we have with our colleagues in nursing and medicine.
ABSTRACT
It has been known to the public that high frequency of false and/or unnecessary alarms from patient monitoring devices causes “alarm fatigue” in critical care. But little is known about the impact to care on the less acute patients located outside the critical care areas, such as the traditional medical/surgical (med/surg) floor.

METHODS: As part of a larger population management study, we initiated continuous physiological monitoring to 79 beds of floor patients in a community hospital. In order to qualify the patient monitoring alarm load for subacute medical and surgical floor patients, we assessed alarm data from April 2009 to January 2010. A standard critical care monitoring system (Philips IntelliVue MP-5 and Telemetry) was installed and set to the default alarm limits. All waveform data available for the patient (typically ECG, RESP, PPG at 125hz 8 bit), all alarm conditions declared by the monitoring system, and 1 minute parameter trend data were saved to disk every 8 hours for all patients. A monitoring care protocol was created to determine whether the patient was monitored via the hardwired bedside or wirelessly via telemetry. Alarms were not announced on the care unit but instead notifications were the responsibility of remote telehealth center personnel. We retrospectively evaluated the frequency of alarms over specific physiologic thresholds (n= 4104 patients) and conducted adjudication of all alarms based on a smaller sampling (n=30 patients).

RESULTS: For all patients, the average hours of monitoring per patient were 16.5 hours with a standard deviation (s) of 8.3 hours and a median of 22 hours. The average number of alarms (all severities) per patient was 69.7 (s =90.3, median =28) alarms. When this is adjusted to the duration of monitoring, the average per patient, per day rate was 95.6 (s =124.2, median =34.2) alarms. The adjudicated sample (n=30 patients) resulted in 34% of critical alarms (lethal arrhythmias, extreme high or low heart rate [HR], extreme desaturation, apnea) being true and 63% of the high priority alarms (high or low HR, high or low RR, Low SpO2, pause, Missed Beat, Pair PVCs, Pacer Not Pace, Non Sustain VT, Irregular HR, Multiform) being true. Analysis of alarm history resulted in the ability to reduce the HR alarm load by more than 50% with a simple limit adjustment of high HR from 120 to 130 bpm and a 36% or 65% reduction in SpO2 alarm load by reducing the SpO2 limit from 90% to 85% or 80% respectively.

CONCLUSION: 1) Standard critical care alarm limits appear to be too sensitive for subacute care areas of the hospital. 2) For most patients these alarm limits do not create a significant alarm load; however, for a small number of patients they cause a significant alarm load. 3) Alarm loads can be controlled with alarm limit settings appropriate to the population. 4) Current technology for HR and SpO2 appear suitable for continuous monitoring of this population.
Clinical alarms are intended to draw attention to a significant event so that timely and appropriate action can be taken to avoid an adverse outcome. In the critical care environment, high sensitivity and specificity are designed into the alarms based on pretest likelihood of certain events and a zero clinical tolerance for false negatives. Unfortunately, this also results in frequent false and/or unnecessary alarms. In environments where the care process is either unable or unwilling to adjust limits, alarm fatigue has been shown to desensitize the care team to the alarms that are intended to protect patients.1-6

The term “alarm fatigue” is typically triggered by a superset of false positive alarms, and also true positives that are clinically meaningless alarms (i.e., clinicians take no clinical action). The fatigue problem stems from the high ratio of false positive and clinically meaningless true positive to clinically significant true positive alarms. Over time these alarms are ignored by clinicians who are really looking for clinically significant true positives. In care settings where the care team is close to the patient, the expected workflow to address the alarms may be obvious, but where a distributed care team with a variety of skill levels is deployed, the workflow needs to consider how alarms are distributed, and what clinical skill level is required to assess and address these alarms.

Patients cared for outside the high acuity areas of the facility clearly need physiologic data to detect and prevent patient deterioration.7 In this application area, it is not clear what the optimal sampling of physiologic data is, or which parameters and alert levels are most important for a given patient.7,8 As a result, many healthcare systems are deploying monitoring systems that can acquire aperiodic physiologic data on less acute patients, as well as continuously monitoring more acute patients. Introducing continuous monitoring with traditional parameter limit alarm systems to the floors with higher patient-to-caregiver ratios, lower pretest likelihood for the events the monitoring systems detect, and in some cases less skilled users can be ingredients for misadventure.

Several studies have quantified the impact in the critical care environment; however, only a few have looked at the impact to the traditional floor environment.9 To explore the balance between the frequency of monitoring observations to detect deterioration, workflow aspects related to technical and parameter alarms, and resulting staff and patient satisfaction issues, we designed a clinical model which uses continuous physiologic data acquisition feeding a remotely located telehealth population management system and assessed alarm limits and workflow impact.

Methods
A community hospital located in urban Arizona and the entire facility’s 79 med/surg beds were selected for this study. With Institutional Review Board approval, each room was instrumented with a two-way audio/video telepresence system and population management system (eICU, VISICU Philips Healthcare), a critical care bedside monitor (Intellivue MP5, Philips Healthcare) and a bidirectional WMTS telemetry system (IntelliVue Telemetry System, Philips Healthcare).

The monitors in patient rooms were configured with a custom screen and profiles (a collection of measurement, display and monitor settings) such that they normally operated as “spot check” monitors by primarily displaying tabular trend information and only used a color-coded bezel light to display the highest priority active alert. The monitors were additionally configured with a profile to support signal troubleshooting and for a more traditional real-time display of parameters, waves, and alarms in the case of patient degradation or a need to troubleshoot signal quality issues.

The floor nursing staffs were educated on the basic setup, troubleshooting, and spot check vital acquisition operation of the monitoring system. The floor staff were not educated on advance arrhythmia interpretation as these data were not displayed anywhere on the care unit, other than during troubleshooting and deterioration events. In both of these cases, representatives from the telehealth center and clinical personnel skilled in advanced arrhythmia were in attendance.

The remote telehealth center was notified of critical alarms via a “bed-to-bed overview” client and near real-time web interface from the monitoring system. A central station client (IntelliVue Information Center Central Station, Philips Healthcare) was used in the telehealth center as a control interface for patient admit,
discharge and transfer operations, optimization of alarm and algorithm settings, and to support electronic data download to the site’s charting system, as well as separate proprietary alert prompts running in the telehealth center via the HL-7 physiologic data feed. While the bedside devices detected and announced parameter alarms, only the highest severity events were announced to the remote telehealth center in real time. The other lower priority alarms were not displayed to the care team but were stored in the data used for analysis.

The bedside system was configured to report only critical arrhythmias (asystole, ventricular tachycardia, ventricular fibrillation) and severe physiologic limit violations (severe desaturation, severe bradycardia, severe tachycardia, and apnea >30 seconds). Additionally the monitoring system was configured to reported significant technical alarms such as “ECG Leads Off” and “Replace Battery” messages to the remote telehealth center personnel, where they were triaged and if necessary, dispatched to the floor-based team or in some cases, the patient for rectification.

As part of a larger population management study, we initiated a baseline workflow of continuous physiological monitoring for all patients on the 79 beds. The choice of device was driven by the ambulatory needs of the patient; however, the care process called for continuous monitoring of at least SpO₂ (pulse oximetry) and pulse rate for all patients. All new admissions and post-operative patients required electrocardiogram (ECG), SpO₂, blood pressure, temperature and respiration monitoring. Ambulatory patients did not require the respiration parameter. Patient-specific aperiodic monitoring of temperature and blood pressure were determined by care requirements previously established on the floors.

The initial workflow for alerts included the remote telehealth center receiving immediate notification of critical events and investigating the sourcing alert data. If the alert was considered of clinical value, the telehealth center would either contact the patient directly via the two-way telepresence system (voice and video), contact the patient’s nursing assistant (for technical events), or contact the patient’s nurse via the in-building wireless phone system. For the 79 med/surg beds, the remote telehealth
group consisted of two experienced med/surg RNs who were trained in arrhythmia interpretation. The team monitors patients 24 hours a day, observing vital signs and test results to ensure appropriate care for medical and surgical patients. Additionally, they conduct daily “virtual” rounds on patients to review orders, test results, and discharge plans, and ensure that all appropriate evidence-based protocols are in place. When appropriate, they can communicate “face to face” with patients and staff in the patient’s room through a two-way video system that includes a camera and monitor.

In order to quantify the alarm load for subacute med/surg floor patients, we automatically saved all physiologic data for later review. The data consists of all monitored waves as 125 samples per second (sp/s), 8 Bit. Most records include a single lead of ECG, impedance-based respiration via the ECG leads, and a photoplethysmogram (PPG) from the SpO₂ monitor. All alarm and event conditions declared by the monitoring system as well as 1 minute parameter trend data were permanently saved to an external server starting eight hours after admission, continuing until discharge (Research Data Export, Philips Healthcare). We analyzed data from all patients who were monitored on the floors between April 2009 and January 2010 (4,104 patients). We evaluated the physiologic data for alarm rates by parameter, severity, and validity based on an adjudicated subgroup of the population.

**Results**

In the telehealth center where only critical-level alarms were presented, the average number of alarms per patient per day observed by the remote user was 16.1 (s=44.6, median=4.4). Based on the size of the floor units, staffing ratios in the remote telehealth center, and average occupancy, this translates to an average alarm load of 42.3 (16.1*79*0.8/24) and median alarm load of 11.6 (4.4*79*0.8/24) per hour, assuming a unit occupancy of 80%. It is important to note that the median value of alarms per patient per day is only 4.4 while the standard deviation is almost 45. This clearly indicated a skewed distribution and suggests that a small number of patients created most of the alarm load for the users.

During the study period, a separate observational study was conducted to look at workflow, user satisfaction, and patient satisfaction with the test system. While this will be reported

<table>
<thead>
<tr>
<th>Parameter Alarm</th>
<th>“True” criteria</th>
<th>“False” Criteria</th>
<th>“Uncertain” criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>NIBP</td>
<td>(regular R-R as seen on ECG, or PPG waveform) AND (no significant ventricular ectopy) in the 60 seconds leading up to the measurement</td>
<td>(irregular R-R as seen on ECG, or PPG waveform) or (significant ventricular ectopy) in the 60 seconds leading up to the measurement</td>
<td>If the analysis of the data did not result in either aforementioned classification, or did not have any other corroborating data at the time of the event</td>
</tr>
<tr>
<td>SpO₂</td>
<td>(good PPG waveform at a constant signal level) AND (clear incisura or dicrotic notch) AND (no obvious motion artifact or noise) AND (ECG HR within 5% of PPG based Pulse).</td>
<td>(poor PPG waveform at an inconstant signal level) OR (no clear dicrotic definition) OR (obvious motion artifact / noise) OR (ECG HR not within 5% of PPG based Pulse)</td>
<td>If the analysis of the data did not result in either aforementioned classification, or did not have any other corroborating data at the time of the event</td>
</tr>
<tr>
<td>Resp</td>
<td>(cardiac overlay &lt;25%) AND (no significant noise or artifact on ECG) AND (no significant noise or artifact on RESP).</td>
<td>(cardiac overlay &gt;25%) OR (significant noise or artifact on ECG) OR (significant noise or artifact on RESP)</td>
<td>If the analysis of the data did not result in either aforementioned classification, or did not have any other corroborating data at the time of the event</td>
</tr>
<tr>
<td>ECG and HR</td>
<td>(no significant noise or artifact on ECG) AND (good R-R correlation to PPG) AND (no significant noise or artifact on RESP).</td>
<td>(significant noise or artifact on ECG) OR (poor R-R correlation to PPG) OR (significant noise or artifact on RESP)</td>
<td>If the analysis of the data did not result in either aforementioned classification, or did not have any other corroborating data at the time of the event</td>
</tr>
</tbody>
</table>

Table 1. Adjudication criteria of alarms based on prior 30 seconds of physiologic wave and trend data. NIBP = noninvasive blood pressure; SpO₂ = pulse oximetry; Resp = respiratory rate; ECG = electrocardiogram; HR = heart rate; R-R = ECG R to R wave interval; PPG = photoplethysmogram
Health professions have varying requirements and skills sets. And these can differ from state to state and facility to facility. It’s a dilemma we all share. Surgical technology confronted the need to retain specific skills sets, address the evolving roles and responsibilities related to the 21st century as well as establish a common benchmark with one foundational resource for our educational programs.

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separately, this study showed that the monitoring system was responsible for approximately 30% of the interruptions to care in the telehealth center. Of those monitoring-triggered interruptions, only 20% were true and clinically meaningful and resulted in a clinical intervention, such as the telehealth center asking the staff or patient to put the oxygen delivery device back on, for the staff to check or replace ECG electrodes, or for a change in care. To better understand this, we identified patients who were admitted prior to midnight the day before the observation days (n=63 patients) and adjudicated alarms (critical and high priority) on a randomly selected subgroup (n=30 patients). The alarm adjudication was based solely on the presence of the clinical event reported by the monitoring system and was not based on the actionability of the event based on evidence in the clinical record. During the observation period, 4,393 alarms resulted from 1,040.5 total monitoring hours, and 2,218 alarms were adjudicated from the resulting 529.5 hours based on the random sample. These alarms were reviewed by two independent clinical researchers for validity. In the case of disagreement, a third judge was utilized. Table 1 summarizes the validation criteria used.

<table>
<thead>
<tr>
<th>Alarm</th>
<th>Raw count</th>
<th>Rate (per patient, per day)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TRUE</td>
<td>FALSE</td>
</tr>
<tr>
<td><strong>SpO2 Low</strong></td>
<td>505</td>
<td>196</td>
</tr>
<tr>
<td><strong>RR Low</strong></td>
<td>141</td>
<td>345</td>
</tr>
<tr>
<td><strong>HR High</strong></td>
<td>265</td>
<td>0</td>
</tr>
<tr>
<td><strong>HR Low</strong></td>
<td>128</td>
<td>13</td>
</tr>
<tr>
<td><strong>RR High</strong></td>
<td>87</td>
<td>25</td>
</tr>
<tr>
<td><strong>Pulse High</strong></td>
<td>13</td>
<td>9</td>
</tr>
<tr>
<td><strong>Irreg HR</strong></td>
<td>20</td>
<td>0</td>
</tr>
<tr>
<td><strong>Pulse Low</strong></td>
<td>0</td>
<td>14</td>
</tr>
<tr>
<td><strong>Pair</strong></td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td><strong>NBP High</strong></td>
<td>4</td>
<td>0</td>
</tr>
<tr>
<td><strong>NBP Low</strong></td>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td><strong>Pause</strong></td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td><strong>Non-Sustain VT</strong></td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total High Priority</td>
<td>1171</td>
<td>610</td>
</tr>
</tbody>
</table>

Table 2. Critical alarm raw count and rate from adjudicated review (desat=desaturation; VT/VF=ventricular tachycardia/ventricular fibrillation; brady=bradycardia)

<table>
<thead>
<tr>
<th>Alarm</th>
<th>Raw count</th>
<th>Rate (per patient, per day)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>TRUE</td>
<td>FALSE</td>
</tr>
<tr>
<td>*<strong>APNEA</strong></td>
<td>74</td>
<td>140</td>
</tr>
<tr>
<td>*<strong>DESAT</strong></td>
<td>37</td>
<td>42</td>
</tr>
<tr>
<td>*<strong>TACHY or VT/VF</strong></td>
<td>8</td>
<td>13</td>
</tr>
<tr>
<td>*<strong>BRADY</strong></td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>*<strong>ASYSTOLE</strong></td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>Total Critical</td>
<td>119</td>
<td>209</td>
</tr>
</tbody>
</table>

Table 3. High priority alarm raw count and rate from adjudicated review
day are shown in Figure 1 and Figure 2 respectively.

There were a total of 13.1 critical alarms/patient/day (s = 21.4, median = 6.0) with 34% of these alarms being true based on alarm adjudication. Table 2 demonstrates the alarm with the greatest frequency was ***APNEA (average true rate = 2.6, average false rate = 4.7; 33% True). This was followed by ***DESAT (average true rate = 1.2, average false rate 1.7; 39% True) and by ***TACHY or VTACH (average true rate = 1.0, average false rate 0.4; 38% True). It should be noted that most of the ***TACHY alarms with heart rate over 160 are false. The breakdown for the 1,864 high-priority alarms, had they been announced to the user, was an average 82.5 alarms/patient/day (s = 122.9, median = 22.7) with 63% of these alarms recorded as True. Table 3 demonstrates the alarm with the greatest overall frequency was **SpO2 Low (average true rate = 17.9, average false rate 7.2; 66% True).

While there are clearly opportunities for algorithm improvements to monitor these patients, we believe that today’s ECG and SpO2 technologies are viable to monitor this population. Additionally, we have seen several cases where arrhythmia monitoring resulted in new actionable clinical knowledge. However, the positive predictive value of this monitoring is low. Based on the relatively low pre-test likelihood, and the fact that only a single vector of ECG is monitored in this environment, we recommend a patient risk-based approach rather than blanket arrhythmia monitoring in the sub-acute care areas. At the very most, we would recommend using only limited or basic arrhythmia monitoring. We further conclude that while the sensitivity of impedance respiration may be too high for this population, the parameter does provide value in this setting based on the raw true alarm count. The raw number of true apnea alarms indicates that this may be a useful screening application for sleep apnea and hypopnea.

SpO2 high priority and critical alarms are linked by a SpO2 offset level and persistence delay. Similarly HR high and critical alarms are linked by a delta HR level. This implies two items. First, alarms shown in Figures 3 and 4, which annunciated below the severe SpO2 value of 80% or above the severe high HR of 140
bpm, are critical alarms. And second, by moving the low SpO₂ and high heart rate “high priority” limit, there will be a concurrent reduction of the severe alarms.

The frequency of critical and high priority alarms is predominately caused by two or three specific alarms in each priority. Further, analysis of alarm history resulted in the ability to reduce the high HR alarm load by 35% by increasing the default limit adjustment of high HR from 120 to 125 bpm, and by 52% with a simple limit adjustment of high HR from 120 to 130 bpm (assuming the severe tachy limit stays at 130). A 36% reduction in SpO₂ alarm load will be seen by reducing the high priority SpO₂ limit from 90% to 85% and further reducing the critical SpO₂ 65% with a limit reduction from 90% to 80% (assuming the severe desaturation alarm stays at 80%).

Unfortunately the duration of physiologic events is not easily extracted from the data, and time correlation to therapy analysis is ongoing. A sustained SpO₂ of 80% was not accepted by this clinical community as an acceptable alarm limit; however others have found a low and persistent SpO₂ alarm at 80% acceptable.⁸

Clearly these are very simple changes that significantly reduce the raw number of critical and high-priority high HR and low SpO₂ alarms. Work is underway to ascertain the sensitivity and specific of these new alerts limits related to clinical interventions and actual patient deterioration.

Conclusion

Standard critical care alarm limits may be too sensitive for subacute care areas of the hospital, but alarm loads can be controlled with limit setting starting first with limits appropriate to the population and then possibly from fine tuning to the specific patients who create excessive false or non-actionable alarm loads.

References


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ABSTRACT

Cardiopulmonary monitors (CPMs) generate false alarm rates ranging from 85%-99% with few of these alarms actually representing serious clinical events. The overabundance of clinically insignificant alarms in hospitals desensitizes the clinician to true-positive alarms and poses significant safety issues. In this IRB-approved externally funded study, we sought to assess the clinical conditions associated with true and false-positive CPM alarms and attempted to define optimal alarm parameters that would reduce false-positive alarm rates (as they relate to clinically significant events) and thus improve overall CPM performance in critically ill children.

Prior to the study, clinically significant events (CSEs) were defined and validated. Over a seven-month period in 2009, critically ill children underwent evaluation of CSEs while connected to a CPM. Comparative CPM and CSE data were analyzed with an aim to estimate sensitivity, specificity, and positive and negative predictive values for CSEs.

CPM and CSE data were evaluated in 98 critically ill children. Overall, 2,245 high priority alarms were recorded with 68 CSEs noted in 45 observational days. During the course of the study, the team developed a firm understanding of CPM functionality, including the pitfalls associated with aggregation and analysis of CPM alarm data. The inability to capture all levels of CPM alarms represented a significant study challenge. Selective CPM data can be easily queried with standard reporting, however the default settings with this reporting exclude critical information necessary in compiling a coherent study denominator database. Although the association between CPM alarms and CSEs could not be comprehensively evaluated, preliminary analysis reflected poor CPM alarm specificity. This study provided the necessary considerations for the proper design of a future study that improves the positive predictive value of CPM alarms. In addition, this investigation has resulted in improved awareness of CPM alarm parameter settings and associated false-positive alarms. This information has been incorporated into nursing educational programs.
Cardiopulmonary monitors (CPM) are currently designed with flexible alarm parameters to warn providers about patient conditions, events, or devices that deviate from a predetermined “normal” status.1 When an alarm is triggered, the provider is expected to respond to the alarm, identify its cause, and intervene as necessary.2,3 According to the American College of Clinical Engineering (ACCE) Healthcare Technology Foundation, clinical alarms should deliver information that is accurate, intuitive, and provide alerts which are readily interpreted and acted on by clinicians.4 However, the ACCE Healthcare Technology Foundation reported that CPM alarms were not performing as expected because of a complex set of interdependent issues.4

Some alarms may reflect a change in the patient’s condition (true-positive) while many others are not clinically significant and/or reflect poorly set monitoring parameters (potentially causing false-positive/nuisance alarms).3 A false-positive or clinically insignificant alarm is defined as an alarm that occurs in the absence of an intended, valid patient or alarm system trigger.4 The sheer volume of clinically insignificant alarms in the hospital setting is an important safety issue.5 False-positive alarm rates have been reported ranging from 85%-99% with few representing significant clinical events requiring provider intervention.4,6 In one report, the number of alarms in a medical progressive care unit was documented during an 18-day period (patient census of 12). The number of alarms totaled 16,953, or 942 alarms/day with one alarm occurring every 92 seconds.7 Data from one of our critical care units in 2009 were similar over a 30-day period (patient census of 35). A total of 39,000 alarms occurred or 1300 alarms/day and one alarm sounding every 66 seconds.8

The overwhelming number of false-positive alarms has been likened to the Aesop’s fable of the boy who cried wolf.9 Alarm fatigue can occur when the large number of monitor alarms overwhelms and desensitizes providers7, causing them to divert attention away from clinically significant events.3 With such fatigue, providers often ignore the sound, lower the volume, extend alarm limits outside of a reasonable range, or disable the alarms.5,10,12

Paradoxically, CPM may contribute to the generation of adverse patient events. Because of the disproportionate number of false-positive alarms, there is a lower likelihood of effectively responding to an alarm if the false-positive alarm rate is high.2,11,12 Despite regulatory and accreditation guidelines regarding CPMs established by The Joint Commission in 2002, CPM-related adverse events including patient death continue to occur.11 Although reporting of sentinel and adverse events is sparse in the literature, the authors have experienced incidents of inattention to alarms with significant adverse patient outcomes.

We conducted an eight-month study on multiple units at our pediatric medical center and found that the mean monitor alarm response time exceeded three minutes in 50% of the cases (range 25-65%).14 These findings led to the assignment of a monitor technician stationed at a central monitoring bank for the purposes of notifying nurses of CPM alarms. These efforts did not result in any detectable improvement in provider alarm response time. In addition, at our institution, although the CPM alarm parameters are to be ordered by a physician or licensed independent prescriber every 24 hours, a recent evaluation documented poor compliance with this policy with less than 50% of our physicians/providers ordering CPM parameters.14

In this study, a team of nurses, biomedical engineers, physicians, and biostatisticians was assembled to develop a project to assess the conditions associated with the generation of CPM alarms including false-positive alarms in critically ill children. In addition, this team set out to define alternative alarm parameters that would improve CPM alarm generation performance. We hypothesized that the sensitivity, specificity, and positive predictive value of CPM alarms could be optimized resulting in a significant reduction in false-positive alarms. The purpose of this article is to describe the study methodology, lessons learned, and implications for future research and practice.

Study Aims
The specific aims of the study were to:
1. Compare CPM alarms to clinically significant events (CSEs) in the pediatric intensive care unit (PICU) to estimate sensitivity and specificity of alarms based on current procedures.
2. Improve the performance of the CPM alarm...
system by using a statistically guided approach for manipulating alarm settings for the optimized triggering of true-positive and true-negative signals for CSEs, and thereby, minimizing the rate of false-positive alarms.

Methods

Inclusion Criteria
This externally funded study was approved and deemed exempt by the hospital’s Institutional Review Board. The study was conducted in a 24-bed, Level I Pediatric Intensive Care Unit (PICU) with an average daily census of 20 children. All children with severe or potentially life-threatening diseases and those with multisystem as well as postoperative severe conditions were eligible for inclusion in the study. Patients were excluded from the study if they were admitted pending organ donation, were admitted for less than 12 hours, or had an anticipated length of stay of less than 24 hours.

Clinically Significant Event (CSE)
A focus group of PICU nurses was convened to explore and develop the definition of a CSE. The nurses were asked to describe what types of patient events prompt a monitor alarm, what types of clinical events require them to intervene on the patient’s behalf, and to describe the times when their patients may have had a CSE but the nurse was not alerted by a CPM alarm. From this consensus work, a CSE was defined as an event that requires intervention without which the patient’s condition would worsen or deteriorate.

CSEs were confirmed by the research data collection nurse and bedside nurse and then recorded. Events or data that were in question or difficult to interpret were reviewed by two coinvestigators and two independent critical care nurses and physicians for analysis and adjudication.

Cardiopulmonary Monitoring Equipment
The bedside CPM devices used for the study were the same devices used for patient care (Philips MP70 devices with individual parameters available for heart rate, cardiac monitoring, pulse oximetry, non-invasive blood pressure measurement, invasive pressure measurements, temperature, and respiratory rate). The bedside devices (MP70) were connected to a networked central station (Philips Patient Information Center - PIC) that saved vital sign results, graphs, and alarm data associated with each monitor on a database server and were automatically exported from the database server to the Philips Research Data Export Tool every four hours and stored indefinitely for all patients in the PICU. A script was used to extract patient information from the database and store it in a lookup table. These data were electronically filed by patient lookup number on the system server until a potential study patient was identified. When a study patient was identified, biomedical engineering extracted the two files associated with that patient (alarm file and vital signs file) and sent them to the study coordinator.

The alarm file was a text file containing a time stamp and a description of the alarm that occurred and the type of alarm (Philips classifies alarms as one-, two-, or three-star alarms). Three-star alarms were defined as a cardiac arrhythmia, apnea, or oxygen desaturation; two-star alarms were defined as vital signs that exceeded high/low parameter settings; and one-star alarms represented equipment alerts. There were two available files for each device (patient): a list of alarms and a minute-by-minute table for all of the vital sign parameters that were measured. The specific data sent from the monitor to the research data export tool were configured at the PIC central station.

The vital signs file was a text file listing the measured vital signs in one-minute intervals and only displayed/recorded vital signs that were being measured by the patient monitor. For example, the vital signs for non-invasive blood pressure were not displayed if that blood pressure connection was turned off on the monitor. The one-minute vital sign recorded was an average of the vital signs measurements over that one-minute period.

Outcome Measures
There were three routes of data acquisition: direct data recording witnessed by the research data collection nurse; indirect data recording
obtained from the bedside nurse when not observed by the data collection nurse during the study period, and extraction through daily electronic medical record review.

Prior to the collection of data, a standardized case surveillance data sheet (i.e., the monitor data collection form) was developed and piloted with the research data collection nurses trained to perform study functions. The case surveillance data sheet was then refined to accommodate clinically necessary changes and add validity to the measures being recorded. Data collected were recorded on the form shown in Table 1.

In addition, data from the CPM were collected for each patient for up to 72 hours per patient using Philips Intellivue Trend and Alarm monitor query software to allow full disclosure review of data. CSEs were characterized independently of the CPM alarms. There was no attempt at the bedside to establish whether an alarm was a false- or true-positive alarm. That decision was based solely on whether the alarm was coincident or occurred within several minutes of the CSE. Occurrence, type, and timing of alarms were based on the CPM data retrieval and analysis during the observation period.

Data collectors were trained on how to complete the case surveillance data sheet to promote a standard methodology that minimized variability. The principal investigator met regularly with the data collectors and provided oversight and periodic review of data collection. The PICU staff were provided with an overview of the study purpose and design.

**Procedure**

At the beginning of each direct data observation, the research data collection nurse notified Biomedical Engineering of the need to extract CPM data for all eligible patients enrolled in the study that day. Demographic and clinical data were then recorded for each patient. Data collection rounds were performed at least hourly. The direct data observation periods ranged from two hours to seven hours (average five hours) per day over the course of three days per patient. The bedside nurses were informed of the patient’s participation in this study in order to provide the necessary data.

Table 1. Clinically Significant Event Observation Form, © 2011, Children's National Medical Center, Washington DC.

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study and were asked to report CSEs not observed by the data collector during the direct data recording period.

**Data Analysis**

In aim 1, cross tabulations were developed to assess the sensitivity, proportion positive by the gold standard CSE that are CPM positive, and specificity, proportion negative by the gold standard that are CPM negative and set the 95% confidence interval (CI) around each estimate. We defined cut-points for acceptable levels of sensitivity and specificity. In addition to an overall analysis based on all types of CSE, we planned to estimate sensitivity and specificity for selected subtypes of these events. The purpose behind this type of subgroup analysis was to identify whether CPM performance varied greatly by subtype of event.

For aim 2, we planned to use receiver-operator characteristic (ROC) analyses on each CPM clinical parameter being monitored to identify the best cut-point(s) to maximize sensitivity and specificity for CSEs overall and by subtype. ROC analysis was used to evaluate sensitivity versus 1- specificity (false positivity) associated with moving the cut-point for signaling an event warning (alarm) across the full range of values of each monitored parameter. Based on ROC analysis, we planned to choose a single cut-point or set of cut-points that met pre-specified criteria. We defined these selection criteria as 1) that set of cut-points for which the specificity was ≥ 70%, and 2) where the sensitivity was ≥ 90%. We intended to repeat this testing for each parameter defining the set of values that met the defined criteria or designate that no such criteria existed.

**Results**

Prior to the study, clinically significant events (CSEs) were defined and validated. Over a seven-month period in 2009, critically ill children underwent evaluation of CSEs while connected to a CPM (MP70, Philips Healthcare, Andover, MA). Comparative CPM and CSE data were analyzed with an aim to estimate sensitivity, specificity, and positive and negative predictive values for CSEs.

CPM and CSE data were evaluated in 98 critically ill children. During the observation period, 2,245 alarms were recorded with 68 CSEs noted in 45 observational days. Types and characteristics of CSEs are noted in Table 2.

<table>
<thead>
<tr>
<th>CSEs</th>
<th>Number of Events (Rate)</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypoxia</td>
<td>36 (53%)</td>
<td>Repositioned x 13</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Adjust O₂ delivery x 12</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Suctioned x 11</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Handbagged x 4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stimulation x 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Medicated x 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Repositioned ETT* x 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Intubated x 1</td>
</tr>
<tr>
<td>Apnea/low RR</td>
<td>12 (17.6%)</td>
<td>Stimulated x 8</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Suctioned x 3</td>
</tr>
<tr>
<td>Combative/agitated pt.</td>
<td>6 (8.8%)</td>
<td>Suctioned x 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Repositioning x 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Extubated x 1</td>
</tr>
<tr>
<td>Hypotension</td>
<td>5 (7.4%)</td>
<td>Increased inotropes x 3</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fluid bolus x 2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stimulated x 1</td>
</tr>
<tr>
<td>Vomiting</td>
<td>4 (5.9%)</td>
<td>Suctioned and repositioned x 4</td>
</tr>
<tr>
<td>Unintended extubation</td>
<td>1 (1.5%)</td>
<td>Rescued and reintubated x 1</td>
</tr>
<tr>
<td>Patient Crying/screaming</td>
<td>1 (1.5%)</td>
<td>Repositioned x 1</td>
</tr>
<tr>
<td>Pain crisis</td>
<td>1 (1.5%)</td>
<td>Medicated x 1</td>
</tr>
<tr>
<td>Hypertension</td>
<td>1 (1.5%)</td>
<td>Decreased inotropes x 1</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>1 (1.5%)</td>
<td>Suctioned x 1</td>
</tr>
</tbody>
</table>

*ETT=endotracheal tube

Table 2. Clinically Significant Event (CSE) Rates and Associated Interventions
During the course of the study, the team developed a firm understanding of CPM functionality, including the pitfalls associated with aggregation and analysis of CPM alarm data. One significant challenge included the inability to query all levels of CPM alarm data. The alarm file for each patient only recorded three-star alarms but did not record the one-star and two-star alarms secondary to a setup issue with the Philips central station. Accordingly, the association between CPM alarms and CSEs could not be fully evaluated with the anticipated ROC analyses.

Investigational time stamps were also noted to be problematic in that the time posted on the data collection sheets did not always match the time on the two study files and were in error by up to four minutes. The Philips bedside monitors, the Philips database server, and the hospital time devices (computers and phones) were not problematic as they were all on the same time server.

In addition, there were some patients whose medical record number was not recorded on the bedside monitor. Therefore, when there was an attempt to match these two files, they could not be validated and were, therefore, excluded from study analysis.

**Discussion**

CSEs are common in critically ill children. In this study of pediatric critical care patients, it was not surprising to discover that respiratory CSEs, including hypoxia and apnea, comprised the majority of the events.

We set out to examine the relationship between CPM and CSEs.

The largest impact to the study was related to the recording of alarms. Although CPM data can be easily queried, reporting configuration default settings can exclude critical information that is necessary in compiling a coherent denominator database.

During the study, we were unaware that all alarms were not saved into the alarm file because the central station patient information

This investigation has resulted in improved awareness of CPM alarm parameter settings, associated false-positive alarm rates, and the potential impact on quality care delivery.
center was defaulted to send only three-star alarms to the research data export tool to limit the file size. Because this issue was not identified by the research team until all study data had been collected, the data stored did not definitively identify all alarms that occurred with each study patient. As a result, our inability to capture all relevant CPM data impeded our ability to rigorously test the relationship between CPM and CSEs. Initial impressions, however, from this investigation are that many, but not all, CSEs can be detected with the CPMs currently in use.

This investigation has resulted in improved awareness of CPM alarm parameter settings, associated false-positive alarm rates, and the potential impact on quality care delivery. In addition, this information has been incorporated into an annual education for all nursing staff regarding bedside monitoring.

Because of the complex and interdependent issues involved in CPM alarms, we believe one of the strengths of our project was the interdisciplinary nature of our study team. The clinical and technical expertise and contributions of our frontline and research nurses, biomedical engineers, physicians, and biostatisticians were critical in expanding our knowledge and understanding of the relationship between CPM alarms and CSEs.

Implications for Future Research and Practice
CPM devices are physiological parameter screening tools that attempt to identify patients whose condition is deteriorating for early preventative intervention. There are well-established criteria for the use of clinical monitoring screening tools. We recommend that researchers consider these criteria in designing future studies.

First, the screening outcome should be an important patient-specific health issue. Clearly, CSEs in a critically ill population meet this criterion. However, in conducting CPM studies, it is important to clearly define the clinical events that necessitate prevention. In the absence of such clarity, the study methodology would likely characterize clinical deterioration only in terms of the monitor setting parameters. In the current study for example, one type of CSE was defined as oxygen desaturation. In this case, data also could be recorded to determine whether deterioration is occurring based on the patient’s clinical status.

Second, the investigative team should have a clear definition of whom to screen for the study. In this study, most patients were included if admitted to the PICU, despite marked variability in severity of illness and, therefore, the likelihood of developing a CSE.

Third, there should be an acceptable treatment or preventative intervention that alters the outcome should a CSE occur. For example, performing tracheal intubation for a patient who develops apnea would represent such an intervention, whereas it is not clear that calming a crying child who has developed tachycardia represents an intervention of the same importance.

Fourth, there must be a valid and acceptable screening test that will identify persons at risk of a CSE in which an intervention can be applied successfully. A valid monitoring tool must have adequate sensitivity and specificity. In this preliminary analysis, it appears that the CPM, as currently used, has high sensitivity but poor specificity and, therefore, a high false-positive rate.

Despite the analytical challenges, several important findings in our study design were illuminated for future investigation:

- improved methodology in conducting the next iteration of this study so that all appropriate monitor alarm categories are accurately and reliably captured to ensure comprehensive data analyses,
- appropriate design in defining and measuring CSEs in the PICU,
- the relationship between PICU CSEs and CPM data.
References


Statement of Financial Interest
Funding from Philips Healthcare for this study was awarded to Linda Talley, MS, RN as the principal investigator and director of nursing at Children's National Medical Center in Washington DC on August 20, 2007. Funds were used primarily to support a portion of the principal investigator's salary, data collector's salary, and biostatistical analysis fees.
To help clinicians make evidence-based decisions about where to program alarm settings, Masimo Corp. based in Irvine, CA conducted an analysis of 32 million pulse oximetry (SpO2) data points from 10 hospital general post-surgical care areas. Each hospital was equipped with a Masimo Patient SafetyNet™ remote monitoring and clinician notification system, which continuously captures and stores time-stamped SpO2 data with a one-second resolution. This paper reports on the results of a retrospective analysis conducted by the company to determine the incidence of alarms at various alarm threshold and delay settings.

Analysis of the Problem
Alarm hazard has been the first or second “Top 10” technology hazard named by the ECRI Institute in the last three years.¹ The high incidence of false and nuisance alarms in hospital settings has led clinicians to either ignore alarms or defeat them altogether as exemplified by a recent high-profile case in a major tertiary care hospital in Boston.² One emergency department (ED) study reports that less than 1% of alarms were clinically action-able, requiring bedside intervention.¹ Reducing alarm fatigue is a shared responsibility between clinicians, biomedical engineers, and industry. Strategies for addressing this hazard require optimization of the signal path, technology innovation and examination of alarm policies. Pulse oximetry is one of the most common continuous measurements. It is therefore essential to address alarm management for this life-critical vital sign. Innovations in signal processing have significantly reduced alarms by 97% due to motion artifact.⁴ However, many true alarms that do not require clinician intervention contribute to nuisance alarms.

The Johns Hopkins Hospital reduced pulse oximetry alarms by 63% in a step-down unit by reducing the low SpO2 alarm thresholds from 90% to 88%.⁵ Rheineck reported a 60% reduction in low SpO2 alarms in a post-anesthesia care unit (PACU) population by adding a 15-second delay to the 90% lower SpO2 limit.⁶ Dartmouth Hospital achieved more dramatic results by lowering the low alarm threshold to 80% with 15-second delay for continuous patient safety surveillance. Results showed a dramatic reduction in rapid response calls and ICU transfers.⁷
The tradeoffs between SpO₂ low alarm threshold and delay settings have not been described across the full range of low SpO₂ alarm settings and alarm annunciation delays. Automated SpO₂ data collection allows the study of alarm behavior retrospectively for a given patient population. The goal of this evidence-based analysis is to allow clinicians to develop internal policies that optimize alarm behavior and reduce alarm fatigue.

**Factors Influencing SpO₂ Alarms**
The occurrence of alarms is dependent on the integrity of each component in the signal path. A compromised or suboptimal component will result in increased nuisance alarms.

**Sensor Application and Choice**
Proper application of the SpO₂ sensor is critical. An improperly applied sensor is prone to weak signal strength, light interference, or the penumbra effect. Single-patient-use sensors should be used in continuous monitoring applications, especially where low perfusion or motion is common. The lower mass and skin adhesion of single-patient-use sensors improves the coupling of the sensor to the biologic signal. Second-source recycled sensors may provide financial savings, but if not properly refurbished can deteriorate sensor performance and contribute to nuisance alarms. Sensor choices allow a hospital to meet both clinical and financial goals. A broad range of sensor configurations are available, each validated for the intended application. Biomedical personnel should be aware that using sensors outside the instruction for use may impact accuracy. Pulse oximeter manufacturers can provide a list of approved sensors.

**Cable Management**
All cables, regardless of application, have a finite life depending on the environment of use. High-patient-turnover areas like emergency departments and operating rooms are particularly challenging environments. Cable connectors are prone to mechanical stress resulting in intermittent failures that can generate nuisance alarms. Cables should be routinely inspected and replaced on a lifecycle schedule specific to the care area. Intermittent failures are typical of cables approaching the end of their lifecycle and a major cause of nuisance alarms.

**Instrumentation and Signal Processing**
Reducing alarms due to false data (false alarms) is essential to an effective alarm management strategy. Most pulse oximeters perform well with patients who are not moving and have good peripheral perfusion. However, during motion and low perfusion, conventional pulse oximetry can freeze, zero out, or falsely alarm. Freezing or zeroing out can delay the notification of true alarms when the patient may require intervention. False alarms due to motion and low perfusion can significantly increase the total number of alarms so that clinicians become desensitized to true alarms when they occur.

Masimo has developed a new technology for pulse oximeters called Signal Extraction Technology® (SET) which is designed to measure pulse oximetry accurately through motion and low-perfusion conditions. Pulse oximeters embedded in multiparameter monitors that implement SET technology audibly alarm based on three primary factors:

- The displayed SpO₂ and pulse rate value
- The user-defined alarm threshold and alarm notification delay
- Alarm averaging

This means that two multiparameter monitors with the same embedded pulse oximetry technology can have different alarm behaviors.

**Effects of Settings on Alarm Frequency**
A retrospective analysis was conducted to determine the incidence of alarms at various alarm threshold and delay settings. Alarm policies can be determined by collecting high-resolution parametric data that represents a patient population and retrospectively measuring the effects of alternative alarm configurations.

For example, there are instances where alarm thresholds are exceeded for clinically insignificant periods of time, necessitating alarm management strategies that provide clinician-controlled notification delays. Patients in acute care settings can have desaturation events that fall below the traditional alarm threshold of 90% but recover within a few seconds without the need for therapeutic interventions. Figure 1 shows a distribution of SpO₂ values in post-surgical patients on a 36-bed floor over an 11-month period. SpO₂ values less than 90%, the most

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**Technology Overview**
In 2005, Masimo introduced a new technology for pulse oximeters called Signal Extraction Technology® (SET). Conventional pulse oximetry assumes that arterial blood is the only blood moving (pulsating) in the measurement site. During patient motion, the venous blood also moves, which causes conventional pulse oximetry to under-read because it cannot distinguish between the arterial and venous blood. SET signal processing identifies the venous blood signal, isolates it, and using adaptive filters, cancels the noise and extracts the arterial signal, with the goal of reporting the true arterial oxygen saturation and pulse rate.

The Patient SafetyNet® (PSN) remote monitoring and clinician notification system combines this SET pulse oximetry data with acoustic respiration rate monitoring and wireless clinician notification via pager. The devices have a selectable audio alarm delay to reduce bedside noise levels. The bedside devices connect to a PSN server over an isolated biomedical network or the hospital’s main information technology (IT) network, either hardwired or wireless. The PSN server communicates to both a central display as well as an optional direct clinician notification system. Additional alarm delays can be configured for the clinician notification device so that clinicians close to either the central display or the patient can respond to that alarm and avoid a notification. The technology includes a configurable alarm escalation rule set that notifies additional clinicians if the alarm persists.
common alarm threshold setting, occurred 4.4% of the entire monitoring time which equates to an average of 63 minutes per patient per day. Assuming an average desaturation event of 15 seconds, the 63 minutes of alarm condition would result in 250 separate alarms.

**Delay Settings**
Adding a time delay between event detection and the resulting alarm is one of the simplest and most effective methods to reduce alarm occurrence. Separation of events between short-duration and longer-duration alarms can be realized by modest alarm delays. Most desaturations below 90% recover within a short period of time. These self-correcting desaturations represent the vast majority of alarms. Audio delays provide two benefits: They quiet the beside environment, and reduce alarms caused by short desaturation events.

Figure 2 shows the impact of 5, 10, and 15-second delays on the number of alarms at a low SpO₂ threshold setting of 90%. An alarm delay of 15 seconds reduces alarm frequency by 70%.

**Threshold Settings**
The low SpO₂ alarm threshold can also have a significant effect on the number of alarms generated. Ideally, alarm thresholds should be set to the individual patient condition. Modest lowering of the alarm threshold in the absence of any alarm delay can help reduce the total number of alarms generated. Figure 3 shows that lowering the low SpO₂ alarm threshold from 90% to 88% reduces alarms by 45%. Reducing the low SpO₂ alarm threshold from 90% to 85% decreases alarms by 75%.

**Figure 1.** Frequency of SpO₂ values in post-surgical patients. Values under 90% occurred 4.4% of the time. However, very few of these alarms below 90% were actionable.

**Figure 2.** Longer alarm delays can greatly reduce nuisance alarms, assuming such short-duration events are clinically nonactionable.

**Figure 3.** Lower alarm thresholds significantly reduce the occurrence of alarms and should be set according to the severity and risk of the patient population.
Combining Alarm Delay and Threshold Settings

Combining both alarm delays and lower threshold produces the greatest reduction in alarms, as shown in Figure 4. Lowering alarm limits to 88% with a 15-second delay reduces alarms by over 85%. These two settings offer significant alarm reduction while preserving actionable alarms. Using the previous example of 250 alarms per day, setting the low SpO2 threshold to 88% with a 15-second delay would reduce the alarms even further to 15 alarms per patient per day.

Table 1 shows the full range of alarm reductions possible by lowering alarm thresholds and increasing alarm delays, compared to a 90% low SpO2 threshold at a zero-second delay. Alarm delays have a diminishing effect on alarm reduction as alarm thresholds are lowered from 89% to 85%. This table demonstrates that alarm occurrences can be managed through the combination of low alarm and audio delays.

Alarm Averaging

The responsiveness of the numeric display to beat-to-beat changes in SpO2 can be smoothed by averaging the current measured values with previous values. This filtering reduces the low SpO2 data points of short duration desaturation events. Modest changes in SpO2 averaging times have a small impact compared to alarm settings.

Key Terms

| Actionable Alarms: Alarms that require a response to bedside and therapeutic intervention to avoid an adverse event. |
| Alarm Fatigue: Failure to recognize and respond to true alarms that require bedside clinical intervention as a result of high occurrence of alarms. |
| False Alarms: Alarms due to artifact that produce false data. |
| Nonactionable Alarms: True alarms that do not require patient therapeutic intervention. |
| Nuisance Alarms: The high occurrence of clinically non-actionable alarms. |
| True Alarms: Alarms that represent true and accurate physiologic data. |

Figure 4. Impact of combining alarm delay and lower threshold settings. The combined effect of adjusting both settings significantly reduces nuisance alarms in this data set.

Table 1. Percent reduction in alarms at various low SpO2 alarm thresholds and alarm notification delays, compared to a 90% low SpO2 threshold at a zero-second delay.
thresholds and alarm delays at reducing alarm frequency. Modest extensions in averaging times (e.g., from 8 to 16 seconds) can filter out some short duration saturation dips that rebound in a few seconds. Figure 5 illustrates the impact of longer averaging times based on a controlled reference signal. Masimo does not recommend averaging time greater than 16 seconds because it can mask clinically significant desaturations and delay the notification of actionable alarms.

Adaptive Alarms

New alarm technologies hold promise to further reduce unnecessary alarms. Setting alarm thresholds has historically been a one-size-fits-all endeavor. As a result, the alarm behavior of a patient with a normal baseline SpO₂ of 98% is treated by oximeters the same as a patient with a baseline of 93%. In each case, a drop below a low-alarm threshold of 90% will generate an alarm event, though the former case may be a more clinically significant event. This limitation contributes to the number of nonactionable alarms because the same alarm rule is applied to all patients in a given care area.

Setting individual alarms is the recommended practice to reduce alarms, but this effort burdens nursing staff work load. A new alarm concept addresses this challenge by adjusting the audio alarm threshold based on a continuously updating SpO₂ baseline calculation.

Clinicians still set the traditional low SpO₂ alarm threshold and selectively activate the adaptive alarm feature. The algorithm compares the current value against the patient baseline value, the low alarm threshold setting, and a low safety value determined by a configurable setting. If the new SpO₂ value falls significantly from the baseline value an audio alarm activates. If the patient’s baseline drifts towards the low alarm threshold value, the tolerance for audio annunciation narrows.

The benefit of this approach is that audio alarms, which are the major cause of alarm fatigue, automatically adjust to the patient’s baseline value. The sensitivity of the alarm can be increased by lowering the rapid desaturation value.

Table 2 compares the percent reduction in false alarms achieved using the adaptive alarm setting as compared to that achieved with conventional alarm settings using a 15-second delay.

<table>
<thead>
<tr>
<th>Low Alarm Setting</th>
<th>Standard (15 sec delay)</th>
<th>Adaptive Alarm</th>
</tr>
</thead>
<tbody>
<tr>
<td>90</td>
<td>68%</td>
<td>86%</td>
</tr>
<tr>
<td>88</td>
<td>83%</td>
<td>92%</td>
</tr>
<tr>
<td>85</td>
<td>94%</td>
<td>96%</td>
</tr>
</tbody>
</table>

Table 2. A comparison of the percent reduction in false alarms achieved using the adaptive alarm setting as compared to that achieved with conventional alarm settings using a 15-second delay.

* Pending FDA clearance.
Case Study

A recent study conducted on a post-surgical orthopedic floor at Dartmouth-Hitchcock Medical Center in Lebanon, NH and published in *Anesthesiology* demonstrated significant improvements in patient outcomes. The monitoring system reported a 68% reduction in rapid response activations and a 50% reduction in ICU transfers as compared to the previous year. These improvements saved an annual estimated 135 ICU days from this single 36-bed post-surgical unit.

Dartmouth implemented the use model where alarms are sent directly to a clinician pager. The bedside low SpO2 alarm was set to 80% with the audio delay set to 15 seconds at the bedside and 15 seconds before an alarm notification was sent to the clinician device. These settings represent an extreme case compared to the analysis summarized in Table 1.

During the implementation phase, careful attention was focused on selecting the right sensor and optimizing every element in the signal chain including the information technology (IT) wireless infrastructure. Alarms were connected to the assigned nurse through a dedicated paging system. No additional personnel were hired to support the system. The key to this success was a thoughtful alarm management protocol that consistently achieved a performance level of four alarms per patient per day. Approximately half of these alarms were due to sensor removal for patient ambulation. The Dartmouth cross-functional team (which included nurses, physicians, biomed, and IT) were awarded the ECRI Technology Achievement Award for this remarkable achievement. The financial benefits of this pilot project justified extending the system in the hospital to other general care patient populations.

Discussion and Recommendations

Eliminating alarm fatigue is a shared responsibility between clinicians, clinical/biomedical engineers and industry. Clinicians determine policies regarding which patients are monitored and what alarms are set. Biomedical professionals support clinicians by selecting, implementing, and maintaining the best and most cost-effective technology solutions. Both depend on industry to provide technology solutions.

A limitation of the analysis summarized in Table 1 is that true alarms requiring clinical intervention were not captured in this data set. The definition of an “actionable alarm” is subject to hospital definition, but in its simplest form is any alarm that requires a bedside intervention. In this analysis, the worst-case actionable event would be a desaturation to 85% lasting more than 15 seconds. If the low alarm threshold is set to 85% and 15 seconds, then sustained desaturations above 85% would not result in an alarm event. Whether these desaturation events that never cross the low SpO2 threshold setting of 85% are actionable is subject to clinical agreement for the intended patient population. The adaptive alarm technology discussed earlier addresses this at low alarm threshold setting of 90%, which will maintain sensitivity to desaturation events between 85% and 90% but with similar nuisance alarm reduction benefits.

Alarm management extends beyond how the bedside device functions. Alarm management solutions in intensive care areas (where 1:1 patient to nurse ratios are common) differ from those in general medical-surgical wards (where patient to nurse ratios often exceed 6:1). Pulse oximetry solutions in the ICU often involve the selection of a pulse oximetry option provided by an OEM source. The implementation of alarms is the responsibility of the bedside monitor manufacturer and may not necessarily include the same capabilities provided in OEM end-user devices. This is especially true with selectable alarm delays. Biomedical departments should be vigilant in understanding alarm management capabilities when selecting multiparameter monitors.

General care areas require more of a systems approach to alarm management because nurses are typically not at the bedside when an alarm occurs. Patients are more active in the general care area and thus the need for measure-through-motion and low perfusion technologies is greater. Frequent audio alarms at the bedside disrupts the rest cycle of recovering patients. Modest audio delays filter short-duration desaturation events, which reduces nuisance alarms at the bedside without masking the visual alarm indicator should a clinician be in the vicinity.

When an actionable alarm occurs, the assigned nurse needs to be notified so he or she
can respond before the patient further deteriorates. Two systems architectures have emerged:
• Route all physiologic signals back to a remote central surveillance location
• Communicate alarms wirelessly and directly to the assigned nurse

The former has the advantage of using monitoring technicians to interpret alarms and only notify nurses to actionable events. The limitation of this architecture is increased capital and operational cost to sustain the system. If such investments have already been made, adding SpO2 has merit if the SpO2 technology is reliable in high-motion environments.

The alternative architecture directly distributes alarms to the assigned nurse. This option avoids the requirement for monitoring techs to continuously view a central station. However, in this use model, direct notification requires an advanced alarm management capability; otherwise, nuisance alarms are likely to result in system abandonment or user desensitization.

Several companies have introduced wireless “secondary” alarm systems that connect bedside devices to wireless devices. The success of these systems has been limited by the alarm fatigue challenge. Regardless of chosen use model, alarm management strategies are imperative in order to realize any clinical benefit.

Conclusion
Optimizing alarm behavior is a shared responsibility. The analysis in this article provides an example on how to reduce nuisance alarms when implementing Masimo continuous pulse oximetry technology; however the methodology may be applicable to other continuous monitoring technologies. Clinicians can make evidence-based decisions about where to configure SpO2 alarm settings based on the information presented in this analysis for similar patient populations. Optimizing alarm frequency while maintaining notification of actionable alarms can be accomplished with the following alarm settings for the post-surgical general care ward:
• Use single patient use sensors for continuous monitoring applications
• Ensure the integrity of all cables and connectors in the measurement system
• Lowering alarm limits to 88% with a 15-second delay reduces alarms by up to 85%.
• Maintain fixed averaging at 8 seconds

As always, clinicians must ensure proper application of the SpO2 sensor and set alarm thresholds to the individual patient and care setting.

References


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Highlights of the New International Standard

Alarm Systems and Ventilators in Critical Care

Debra R. Milamed and Susan E. Dorsch

In this article, leaders of the joint working group that developed a new international standard for alarms systems and ventilators in critical care report on key provisions of the standard.


This joint working group held its first meeting at the British Standards Institution (BSI) in London in June of that year. The efforts of clinicians, engineers and regulatory authorities’ representatives culminated in publication of IEC 60601-1-8, Medical electrical equipment—Part 1-8: General requirements for basic safety and essential performance—Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems, as an IEC-ISO dual logo standard in 2003.4 This standard was replaced by the second edition in 2006, which aligned it with the 2005 edition of IEC 60601-1 and made the clause numbering adhere to that specified in ISO/IEC Directives Part 2:2004.4,6 In 2010, JWG2 reconvened under the same leadership to revise IEC 60601-1-8 and further address distributed alarm systems, the electronic health record and related concerns.

Early this year, ISO will publish the first edition of ISO 80601-2-12, Medical electrical equipment—Part 2-12: Particular requirements for

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basic safety and essential performance of critical care ventilators. This double logo, ISO-IEC international standard is a Particular Standard, which “may modify, replace or delete requirements contained in the general standard [IEC 60601-1] (as in Subclause 201.1.4), including the collateral standards, as appropriate for the particular medical equipment under consideration, and may add other basic safety or essential performance requirements.”

This new standard was developed by Joint Working Group 1 of ISO Technical Committee 121, Anaesthetic and Respiratory Equipment, Subcommittee 3, Lung Ventilators and Related Devices and IEC Technical Committee 62, Electrical Equipment in Medical Practice, Subcommittee D, Electromedical Equipment, to replace the second edition of IEC 60601-2-12, Medical Electrical Equipment—Part 2-12: Particular requirements for the safety of lung ventilators—Critical care ventilators. The new international standard addresses critical care ventilators and their accessories in the context of a medical equipment system, rather than as stand-alone devices. Significant changes from IEC 60601-2-12:2001 include identification of essential performance for accessories and added requirements for a critical care ventilator as a component of a medical equipment system.

Medical alarm systems have always been important in the intensive care environment. The application of IEC 60601-1-8 to the new international standard for critical care ventilators reaches far beyond its citation as a normative reference (Subclause 201.2).

**History of ISO 80601-2-12**

The Joint Working Group on Critical Care Ventilators of ISO/TC121/SC3 and IEC TC/SC62D (JWG1), with Hedley-Whyte as convener, met at the Swiss Association for Standardization (SNV) headquarters in January 2006 with the task of revising IEC 60601-2-12, under the ISO-IEC Williamsburg-Lübeck Agreement which was adopted in April 2005. This agreement established a framework for closer cooperation between IEC and ISO to

The new international standard addresses critical care ventilators and their accessories in the context of a medical equipment system, rather than as stand-alone devices.
create a series of dual-logo standards, numbered in the 80000 range and distinct from IEC publications numbered 60000 to 79999. JWG1 was established to address critical care ventilators in July 1989 through IEC-ISO cooperation in the development of international standards for medical electrical equipment based on the General Standard IEC 60601-1.3

Highlights of ISO 80601-2-12:2011

Significant changes from the earlier IEC 60601-2-12 standard include broadening the scope (Subclause 201.1.1) to include those accessories (breathing tubes, connectors, humidifiers, and other devices) which may affect the basic safety and essential performance of ventilators and added requirements for a critical care ventilator as a component of a medical equipment system.

Subclause 201.2, normative references, replaces seven IEC standards specified in the general standard as “indispensable” for application of the standard. These address alarm systems (IEC 60601-1-8), electromagnetic compatibility (IEC 60601-1-2:2007), usability (IEC 60601-1-6:2010), environmentally conscious design (IEC 60601-1-9:2007), physiologic closed-loop controllers (IEC 60601-1-10:2007), the home healthcare environment (IEC 60601-1-11:2010), and sound level meters (IEC 61672-1:2002). An additional 40 ISO and IEC international standards to cover critical care ventilators and accessories in an integrated clinical environment are in the normative references, which is supplemented by an informative bibliography.

An important new provision is Subclause 201.103, which requires that a protection device be provided “to allow spontaneous breathing when normal ventilation is compromised as a result of the electrical or pneumatic supply power being outside the values necessary for normal operation.”

ISO 80601-2-12 requires two important new advances in medical information transfer via signal input-output parts. Connection to an electronic health record (Subclause 201.106.2) enables recording, storage and utilization of both patient and ventilator performance data. Connection to a distributed alarm system (Subclause 201.106.3) allows transmission and receipt of data, including the indication of alarm conditions and information signals, outside the immediate location of the patient, e.g. a central nursing station, remote computer or cell-phone. Additionally, in the new international standard, the ventilator may be equipped with a connection for remote, i.e. external control of the ventilator (Clause 201.106.4). Primary operating functions (Clause 206, subclause g) include a pre-use functional check of the ventilator, including the alarm system. Annex AA (informative), Particular guidance and rationale, contains highly informative explanations of many of these new requirements.

Alarm Systems and Critical Care Ventilators

IEC 60601-1-8 (Subclause 3.17) defines a distributed alarm system as one that involves more than one item of equipment of a medical electrical system, and notes that the parts of a distributed alarm system can be widely separated in distance, thereby enabling multiple alarm signal generation and transmission (Subclause 6.11). Such a distributed alarm system can prevent potential adverse events caused by caregiver fatigue, a defect in alarm signal generation or transmission, and other alarm system failures. IEC 60601-1-8 (Subclause 6.11) notes that, “The application of distributed alarm systems is in its infancy. New ideas and new technology are bringing rapid advances and changes in this area. Long-, medium-, and short-range two-way wireless communication opens new opportunities and new challenges for distributed alarm systems.” ISO 80601-2-12 contains a table (Table 201.101) of “Distributed Essential Performance Requirements,” which addresses several alarm conditions.

Clause 208 of ISO 80601-2-12 specifies additional requirements for alarm condition logging, global indefinite alarm signal inactivation states, and termination of alarm signal activation. In addition, it specifies that the ventilator should be equipped with a signal input/output part that permits connection to a distributed alarm system (Subclause 201.106.3).

A major problem with medical electrical equipment is failure of the power supply. The ventilator’s alarm system must include a high
A priority alarm condition to indicate when there is insufficient power to maintain normal operation (Subclause 201.11.8.101.1). If adequate power is being maintained by an alternative, internal power supply, the switchover must be indicated by an information signal or low priority technical alarm condition. A medium priority alarm condition must indicate depletion of the internal power supply, with escalation to high priority at least five minutes prior to loss of all power (Subclause 201.11.8.101.2). A test protocol is provided for testing the alarm condition described above.

The new international standard's broadened scope to include ventilator accessories addresses oxygen monitoring equipment as well. ISO 80601-2-12 requires that the ventilator either be equipped with oxygen monitoring equipment for the measurement of inspiratory oxygen concentration with high and low oxygen level alarm conditions, or that the manufacturer must specify that the ventilator must be equipped with such equipment prior to use (Subclause 201.12.4.101). The new international standard for critical care ventilators specifies alarm signals for low expired volumes; high airway pressures; positive end-expiratory pressure (PEEP); obstruction of a tube, valve or filter; partial occlusion of the expiratory limb; and failure of a gas supply.

A distributed alarm system can prevent potential adverse events caused by caregiver fatigue, a defect in alarm signal generation or transmission, and other alarm system failures.

**Medical Gas Pipeline Systems**

While it is a rare occurrence, failure of an oxygen pipeline presents an emergency situation which can compromise an entire hospital's patient care. Subclause 201.4.11.101.2 addresses the connection of ventilators to medical gas pipeline systems—the subject of numerous standards published by the National Fire Protection Association (NFPA), the Compressed Gas Association (CGA), the Canadian Standards Association (CSA), ISO and others, as well as many local and state codes and regulations. ISO 7396-1:2007 (plus 2010 Amendments 1 and 2), Medical gas pipeline systems—Part 1: Pipeline systems for compressed medical gases is a normative reference, and addresses the rated range of input pressure, and average and transient input flows.

If input flow is outside the parameters specified by ISO 7396-1:2007, then the accompanying documents must contain a warning that the ventilator is a high flow device and should only be connected to a pipeline installation designed using a diversity factor that allows for the indicated high flow at a specified number of terminal outlets, in order to avoid exceeding the pipeline design flow, thereby minimizing the risk that the ventilator interferes with the operation of other equipment. The deployment of distributed alarm systems as part of oxygen and other medical gas pipeline systems will minimize the adverse consequences of alarm failure, disconnection or inappropriate operator response which have been reported in the past.

Annex AA (informative), Particular guidance and rationale, provides a detailed explanation of the international standard's requirements for its pressurized gas supply.

**Role of Standards in Advancing Medical Alarm Systems**

The list of published dual logo international standards developed by joint working groups of IEC TC62 and ISO TC121 subcommittees in the 80601 series continues to increase. The development of a new international standard for critical care ventilators and their accessories built on the general standard and incorporating IEC 60601-1-8 with its requirements for a distributed alarm system and connectivity to an electronic health record, should serve as a model for future standards development work aimed at assisting both clinicians and manufacturers to improve patient safety.
References


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IEC 62D Medical Monitor Standards Will Make Alarms Worse

More than ten years ago, the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) convened a Joint Working Group on alarms (JWG Alarms). The charge to the JWG was to harmonize alarms across all medical devices, in all patient care environments (including home care). After more than five years of hard work, the standard was approved and published: IEC 60601-1-8:2006 Ed.2: Medical electrical equipment, Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (“1-8”). This document established standardized terminology and a framework for alarm function and alarm sounds. In accordance with standards-writing practice, where there was consensus, a standard was created; where there was no consensus, there was no standard defined or alternative methods were permitted.

Now comes a set of new standards from the IEC 62D Committee. We shall focus upon IEC 62D/60601-2-49/Ed.2: Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multi-function patient monitoring equipment (“2-49”). The same serious concerns apply to several other documents produced by this committee.

The 2-49 document devotes more than five pages to rewriting the 1-8 alarms standard. Since the normative section of 1-8 contains only about 16 pages, this is a significant rewrite. In other words, the 62D committee takes exception to the hard work and consensus building of the JWG Alarms, and is rewriting the alarm requirements to its own taste. The result will surely be chaos and confusion, as caregivers...
IEC Subcommittee (SC) 62D of Technical Committee (TC) 62 is responsible for the development and maintenance of particular international standards. Within SC 62D the Working Group MT22 is responsible for particular international standards in the field of electromedical diagnostic and patient monitoring equipment. This includes standards such as IEC 60601-2-49 (multifunction patient monitoring equipment), IEC 60601-2-25 (electrocardiographs), IEC 60601-2-27 (electrocardiographic monitoring equipment), IEC 60601-2-34 (blood pressure monitoring equipment). Within the IEC 60601-1 family, particular standards are intended to set specific requirements for safety and essential performance for a particular group of electrical medical equipment than the general standard (IEC 60601-1) and collateral standards (IEC 60601-1-x) ever could. To achieve this, particular standards add, amend and delete requirements in the general standard and collateral standards.

Experts from around the world with decades of experience in the use, development, manufacturing and testing of patient monitoring equipment are represented in SC 62D/MT22. The most important function of multifunction patient monitoring equipment and other patient monitoring equipment is to provide alarms when a deterioration of the patient is detected, i.e., when limits set by the clinical operator are exceeded. Such equipment is not only used in areas where the patient is continuously attended by healthcare professionals (e.g., in the operating room), but also in areas where the patient is not continuously attended (e.g., intensive care unit). In the latter case, clinicians have to rely on reliable alarming when preset limits are exceeded.

(continued on page 64)
Point-Counterpoint
Continued: IEC 62D
Medical Monitor Standards Will Make Alarms Worse

The 2-49 document devotes more than five pages to rewriting the 1-8 alarms standard. Since the normative section of 1-8 contains only about 16 pages, this is a significant rewrite.

(continued from page 60) will encounter, in the same patient environment, medical devices such as ventilators and infusion pumps, which adhere to 1-8, and other medical devices such as multifunction patient monitors (“monitors”) that do not adhere to 1-8.

The next sections will review some of the many changes made in alarm operation in 2-49.

Possibility of One-Way Alarm Communication

In 1-8, it is permitted to have one-way communication of alarms, provided that notice is given not to rely upon the one-way communication.

As an example, some 20 years ago, one monitor manufacturer used a commercial one-way paging system to deliver alarm messages to doctors and nurses. Nothing was taken away from the regular alarm system, and, even though there were occasional delays and lost messages in the commercial paging system, the company’s data showed that the average response time to an alarm was decreased. (Personal communication, Spacelabs, ca. 1990.) A similar system could be designed via cell phone text messaging.

In 2-49, this possibility of a designated one-way alarm communication system is eliminated because failure of remote communication must generate an alarm. Thus one would have to have a two-way communication system, with greater complexity and greater expense.

Here 2-49 eliminates an inexpensive possibility that has been shown to be beneficial.

Low-Priority Alarm Signals

In 1-8, alarms are divided into high-, medium-, and low-priority. The low-priority alarm means that operator awareness is required, but not operator action. Under 1-8, the low-priority alarm need not have an audible component (a sound) at all, but if it does have a sound, the sound occurs once and does not repeat.

In 2-49, the language is somewhat confusing and contradictory, but the standard appears to demand a repeating sound on low-priority alarms. For example, a repeating sound would be required on “low signal quality” or in the situation in which one electrocardiogram (ECG) wire was loose, but the heart rate and rhythm were still able to be determined.

One of the biggest problems with alarms today is alarm fatigue: the fact that there are so many audible alarms that users do not pay attention to them. The need is not for more alarms; the need is for fewer but better alarms. To require an audible alarm on every low priority alarm is a step backwards because it will take attention away from higher-priority alarms. It should indeed be possible to have an alarm with a visual component only. Even if the monitor is “not continuously attended,” someone should be checking it periodically and should see the visual low-priority alarm. And if an alarm condition truly requires “operator action,” then by definition it is not a low-priority alarm.

Definitions of Alarm Inactivation States

The JWG Alarms wrestled with the names of alarm inactivation states, since historically manufacturers have used many different names such as silence, mute, suspend, disable. The 1-8 document specifies four states:

- Audio Off: Audio alarms do not sound for an indefinite time; visual alarms are still displayed.
- Alarms Off: Audio and visual alarms are not displayed for an indefinite time.
- Audio Paused: Audio alarms do not sound for a definite time (a few minutes); visual alarms are still displayed.
- Alarms Paused: Audio and visual alarms are not displayed for a definite time (a few minutes).

Now 2-49 issues a requirement that visual “technical alarms” (equipment alarms) must be displayed during “Alarms Off” and “Alarms Paused.” These situations, when the visual alarms are displayed, are properly called “Audio Off and “Audio Paused.” Not only does this requirement contradict 1-8, but it defies the logic of the definitions.

Alarm Reset

It should be possible to inactivate the alarms and certainly it should be possible to enable the alarms after the inactivation. The term “Alarm Reset” is problematic, however, because manufacturers have used one of two completely different philosophies on alarms:

1. In the majority of medical monitors made during the last generation, the manufacturers...
recognized that the first operator response to an alarm is to try to make it be quiet. The Alarm Reset function in these monitors would cause the monitor to enter a pre-defined inactivation state. After Alarm Reset, the monitor would be quiet, at least for a period of time.

2. In the minority of medical monitors, the Alarm Reset button terminated existing alarms but immediately enabled the response to new alarm conditions. In these monitors, the device would not necessarily remain quiet.

The 1-8 document recognized these two conflicting uses of Alarm Reset, and also noted that there was no evidence that either approach resulted in monitors that were less safe or less usable than the other. Following the “No consensus means no standard” rule, the JWG Alarms did not mandate one approach or the other. Instead the requirement was that one had to have a way to enter and leave an alarm inactivation state, without specifying the precise mechanism. The only requirement for “Alarm Reset” was to terminate alarms that had cleared, that is, that no longer had an active alarm condition.

Now 2-49 mandates that Alarm Reset must follow the minority approach #2 above. Here are the requirements for Alarm Reset in 2-49:

• Auditory signals for active physiological alarms will be silenced.
• Visual signals for latching alarms that have cleared will disappear.
• Visual signals for active alarms will continue to be displayed.
• The audio and visual alarms are immediately enabled so that new alarms will sound.
• Visual alarms for technical alarms will continue to be displayed.

No requirement is given about what should happen to the auditory signals for technical alarms.

If this operation of Alarm Reset seems confusing to the reader, it seems likely that it will be confusing to the operator as well. How will a caregiver understand how this Alarm Reset supposed to work? Some alarms will disappear and others will not. With many operators familiar with the majority approach and with other equipment at the bedside that follows 1-8, there will be nothing but confusion here.

Distributed Alarm Failure
Under 2-49, if the link to a distributed alarm system (such as a central monitoring station) is disrupted, there must be an audio alarm, even if the monitor is in the “Audio Off” state. This seems logical at first reading, but consider this scenario: A patient has a cardiac arrest and multiple caregivers come to the room to resuscitate the patient. Many alarms are sounding, so the staff puts the monitor into “Audio Off” (as is commonly done in such situations). But now the network to the central station goes down, and so the audio alarm sounds for the communications failure. The staff again activate “Audio Off.” But the communication link is still not working, so—according to 2-49—the alarm must sound again. There is no escape. The staff will not be able to make the alarms be quiet during the cardiac arrest.

This requirement does not appear in 1-8.

Summary and the Future
In conclusion, the new 2-49 standard (and its companion standards from the IEC 62D committee) will create additional alarms and chaos at the patient bedside. Caregivers will be confused by some equipment that follows 1-8 and some that follows the 62D standards. In addition, a future integrated alarm system that would handle alarms from both 1-8 and 62D devices will not be able to replicate the requirements for both kinds of devices.

It is regrettable that the 62D documents have been approved in this form. At a minimum, I wish that they would not be adopted as U.S. standards in this form.

AAMI has recently announced the formation of the AAMI Alarms Committee. I hope that the new committee will be able to set things straight by writing a new U.S. standard that will harmonize the alarms across all medical devices. Of course, that was also the task of the JWG Alarms—a task that was completed successfully in 2006, but now undone by 2-49 and the other standards from IEC 62D.

One of the biggest problems with alarms today is alarm fatigue: the fact that there are so many audible alarms that users do not pay attention to them. The need is not for more alarms; the need is for fewer but better alarms.
Point-Counterpoint
Continued: Changes to the Alarm Standard Are Crucial to Ensure Patient Safety

Experts from around the world with decades of experience in the use, development, manufacturing and testing of patient monitoring equipment are represented in SC 62D/MT22.

Low-Priority Alarm Signals
The alarm standard specifies low-priority alarms as an alarms condition where "operator awareness is required." It does not say that no operator action is required, as Mr. Block stated. How should a patient monitor catch operator awareness in an environment where the clinical staff is not continuously present at the patient’s bedside with no tone or a single tone? That’s not going to work and thus IEC 60601-2-49 requires a repetitive tone for low priority alarms. The other theoretical possibility to make all alarms at least of medium priority was not considered by SC 62D/MT22 because it would not allow users to acoustically distinguish between alarms that require more prompt reaction and alarms that can wait for some time.

The main reason for alarm fatigue is not the auditory component of true alarms, but false alarms which are caused by artifacts and imperfect algorithms. Thus the work should be focused to improve algorithms and to develop intelligent multi-parameter alarms.

Definitions of Alarm Inactivation States
In the opinion of SC 62D/MT22, the usability and patient safety is improved if visual technical alarms are displayed even in the “Alarms Paused” and “Alarms Off” state. “Alarms Paused” and “Alarms Off” are frequently used in situations where the clinical staff cares for the patient such as repositioning and washing because multiple and frequent false patient alarms can be expected in these cases. If, for example, an ECG electrode becomes dislodged from the patient during this procedure, the user will lose ECG monitoring without knowing the cause. Finding out the reason without a hint from the monitor will take longer than with a hint (i.e., a visual technical alarm).

Alarm Reset
SC 62D/MT22 doubts that only a minority of medical monitors used Alarm Reset to terminate existing alarms and immediately enable the monitor to respond to new alarm conditions. Actually, it is convinced that the majority of all current patient monitors have implemented Alarm Reset that way and thus it is a proven concept. What is confusing about a function that does exactly what the alarm standard specifies low-priority alarms as an alarms condition where "operator awareness is required." It does not say that no operator action is required, as Mr. Block stated. How should a patient monitor catch operator awareness in an environment where the clinical staff is not continuously present at the patient’s bedside with no tone or a single tone? That’s not going to work and thus IEC 60601-2-49 requires a repetitive tone for low priority alarms. The other theoretical possibility to make all alarms at least of medium priority was not considered by SC 62D/MT22 because it would not allow users to acoustically distinguish between alarms that require more prompt reaction and alarms that can wait for some time.

The main reason for alarm fatigue is not the auditory component of true alarms, but false alarms which are caused by artifacts and imperfect algorithms. Thus the work should be focused to improve algorithms and to develop intelligent multi-parameter alarms.

Definitions of Alarm Inactivation States
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• Silencing audio alarms of alarm conditions which the user already noticed
• Removing visual alarms messages of alarm conditions that have cleared
• Keeping visual alarm messages of alarm conditions that still persist
• Making the user aware of any new alarms conditions that might occur

Being silent on the exact function of Alarm Reset, like the alarm standard, poses the risk that each manufacturer implements it differently. This will be confusing to operators and increases risk.

Distributed Alarm Failure
How likely is it that the communication link of a distributed alarm system breaks just during the few minutes the patient is in cardiac arrest? Probably, this will not even happen once during the lifetime of the equipment. Furthermore, with the Alarm Reset function as defined in IEC 60601-2-49, the user would hit Alarm Reset and the audible alarm would be silenced and wouldn’t come back unless it is an intermittent problem, e.g., if the network goes down, comes back and then goes down again.

Summary and the Future
In conclusion, the modifications IEC 60601-2-49 and other international particular standards in the field of patient monitoring make to the alarm standard are crucial for patient safety. The requirements in these standards are not new, but have been proven over decades in hundreds of thousands of patient monitors. SC 62/MT22 tried to adopt as much as possible the concepts of the alarm standard and keep the changes to the absolute minimum. It is regrettable that the Joint Working Group on Alarms seems not to accept that there can be specific requirements to the alarm system in a specific group of medical equipment. For the future, I hope that the cooperation of these two committees improves.

Point-Counterpoint
Continued: Changes to the Alarm Standard Are Crucial to Ensure Patient Safety

How should a patient monitor catch operator awareness in an environment where the clinical staff is not continuously present at the patient’s bedside with no tone or a single tone? That’s not going to work and thus IEC 60601-2-49 requires a repetitive tone for low priority alarms.
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Complementing Medical Device Alarms with Animated Guidance

Michael Wiklund and Jonathan Kendler

Caregivers cite medical device alarms as a major annoyance in their work, but also an essential safety net that protects them and their patients from serious harm. When an alarm becomes an annoyance rather than an affordance, it is typically because it does not provide useful information and interrupts important work. False alarms are annoying for obvious reasons, but so are alarm messages that tersely describe problems without hinting at proper ways to resolve them.

Some of the newest medical devices—mainly those with large screens and plenty of computing power—are improving work life for caregivers by guiding them to resolve alarm conditions. For example, an alarm message on a therapeutic workstation might signal the presence of air bubbles in a blood-filled line and provide immediate, step-by-step instructions to remove the air from the blood and restart the therapy. The guidance might even take the form of repeatable animations.

Enhanced guidance, such as animations, can take the stress out of alarm troubleshooting and improve patient care by helping caregivers fix problems quickly.

Slow Progress Toward Better Alarms

Old-school alarm systems, which remain prevalent in clinical environments, have done their best to alert device users to problems by emitting attention-getting tones and perhaps by displaying terse messages on small screens. Often, users disable such alarm systems because they produce too many false alarms or annunciate for invalid reasons given the context of device use (e.g., emitting an air in blood alarm before blood has even flowed into the set). Alternatively, clinicians ignore alarms because of their frequent occurrence and limited value in most scenarios. These problems, most notably alarm fatigue, have led to

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*In The Design of Everyday Things (New York, Currency-Doubleday, 1988), Donald Norman defines an affordance as “…the perceived and actual properties of the thing, primarily those fundamental properties that determine just how the thing could possibly be used…affordances provide strong clues to the operation of things…when affordances are taken advantage of, the user knows what to do just by looking: no picture, label, or instruction is required.”*
several adverse outcomes, prompting a recent series of articles in popular press, including one that reported “Federal investigators concluded that ‘alarm fatigue’ experienced by nurses working among constantly beeping monitors contributed to the death of a heart patient at Massachusetts General Hospital in January [2010].”

More recently, alarm systems in “smarter” medical devices, such as dialysis machines, integrated patient monitors, and infusion pumps, have done a better job of communicating with users. Alarm tones have become more distinctive by conforming to guidance in the International Electrotechnical Commission’s current alarms standard (IEC 60601-1-8:2006), which specifies specific tone sequences based on the device’s class (e.g., general, cardiac, artificial perfusion, ventilation) and the alarm’s importance (high, medium, or low). For example, the standard suggests that a cardiac-related device emit high priority alarms that include a series of three distinct notes forming a major chord (c-e-g) and quickly follow-up with two more notes (g-c) to emphasize the alarm’s high importance. By comparison, the standard suggests that a ventilator should emit audible alarms composed of the musical notes “c,” “a,” and “f” thereby producing an inverted major chord. Recent studies question clinicians’ ability to remember which specific series of notes goes with which device type, but logic suggests that differentiated alarms are better than having every device produce identical “beeps.”

Along with enhanced alarm tones, onscreen messages have also become more informative, with devices moving beyond terse and coded messages such as “Error 43” to more informative messages, such as “Air in line. Pump stopped.” Some device developers have taken the added step of providing troubleshooting guidance on demand (e.g., a button press), which can substantially improve users’ ability to recognize and resolve alarm conditions. Perhaps the simplest way to present troubleshooting guidance is to display text-only instructions for correcting a problem. A small step up from this approach is to include illustrated graphics showing how to perform corrective actions. A larger step up is to animate the corrective actions, which we consider to offer breakthroughs in both effectiveness and appeal to users.

**Bringing Guidance to Life**

In the not too distant past—let’s say the early 2000s—most medical devices lacked the computing power and display size and resolution to present animations. Most medical devices were memory starved and presented information on grayish-green, segmented LCD displays. Their computational poverty constrained developers’ efforts to guide the user effectively.

Today (2011), equipment capabilities are no longer the limiting factor, at least not usually. Limiting factors are now more likely to be a lack of developer initiative and a lack of resources—including both time and money—note that good animations take artistry and a considerable up-front investment. But, the payoff of improved user responses to alarm conditions (i.e., enabling people to fix problems) can be handsome, portending other benefits such as improved device sales and lower demand for customer support.

We have observed the benefits of animated troubleshooting guidance in myriad usability tests of medical devices. In cases where narrative or even illustrated guidance might have left device users struggling to perform corrective actions, an animated demonstration of required actions has enabled test participants to perform the actions with relative ease.

**Advantages of Animation**

Why bother animating corrective actions instead of showing a video? This is a key question because animations are typically more expensive to produce than videos—perhaps two to three times the cost. After all, you need to engage a graphic artist (visual designer) who also has a good feel for teaching to create the animations. The artistic demands posed by creating an acceptable quality video are arguably lower. Animation is superior to video in the same way that drawings are superior to photos—again in most cases—when it comes to delivering instruction. That is why many quick reference guides use graphics (i.e., drawings) instead of photos even though the graphics take more work to produce.
In principle, graphics offer the following advantages:

- Emphasis of important features and subordination or elimination of unimportant ones
- Inclusion of special elements, such as arrowheads or motion lines, to enhance the communication of dynamics
- Inclusion of informative text
- Illustration of features and effects that otherwise are not readily visible
- Elimination of background elements that would create visual noise.

Let’s look at some frames excerpted from an animation of clearing the air from a tube carrying blood from a therapeutic device to an attached patient. Illustrated instructions could use these static images to add clarity to written instructions. However, a continuous animation that includes these sample images makes the discrete steps more coherent, as reflected in the video posted at www.aami.org/HorizonsPlus.

The sample animation was produced on a personal computer using Adobe Flash. However, other applications such as Adobe After Effects, Autodesk Maya, and Swift 3D can also be used to produce equivalent results after investing the varying levels of effort required to learn the applications.

One hallmark of a good animation is that it features simple visuals. Typically, the artist traces reference photos to produce simplified graphical representations of people or body parts and entire devices or specific components. Figure 1 shows this kind of visual translation.

The aforementioned software applications enable the artist to create a motion sequence from one static state to another using a technique that Adobe Flash calls tweening. Figure 2 shows several computer-generated, intermediate frames that “fill the gap” between the end state images created by the artist.

So ask yourself the question: What kind of guidance would you want to receive when responding to an alarm? Your choices in ascending order of preference are likely to be:

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Figure 1. Here, two photos of user-device interactions were converted into colored lined drawings

Figure 2. Two original drawings (far left and far right). The others were created by “tweening” and are the material of an animated sequence

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8 Visual noise is distracting, extraneous visual elements that surround important visual elements. It is akin to electronic noise (e.g., static) that can mask the primary electronic signal (e.g., a radio broadcast).

9 Tweening is the term that Adobe Flash uses to describe the process of graphically interpolating between two visual states, such as two views of an object from different distances and angles.
Error 43
Air-In-Line. Pump Stopped.
Air detected in downstream blood line. Pump stopped. Press Troubleshoot for more guidance.

Note that pressing Troubleshoot, which we’ll presume to be a touchscreen button, will automatically play the animation showing how to remove air from the blood line. You probably would choose the last option, particularly if the corrective action involves many steps. Assuming a device featuring animated guidance (i.e., an advanced help system), here’s what you would need to do in response to an alarm:
1. Acknowledge (i.e., silence) the audio alarm.
2. View the animation that shows how to correct the alarm condition.
3. Correct the alarm condition.

Although animated guidance is a natural complement to alarms, keep in mind that animations are equally well suited to providing procedural guidance.

It usually makes sense to play an animation upon request because experienced users will not need to view it. But, there certainly are cases when playing the video immediately and repeatedly can be advantageous, such as when delivering guidance to users who do not use the device very often (i.e., novices) or when users might not have an extra hand available to press a Troubleshooting button. That said, some animated guidance might have several parts that require users to press a Continue button (or equivalent) one or more times to view in their entirety. If a cycling video segment is likely to become annoying to some users, developers can set it to play only once and include a Repeat button.

Although animated guidance is a natural complement to alarms, keep in mind that animations are equally well suited to providing procedural guidance. For example, one might complement a linear sequence of device set-up tasks with animated demonstrations of the required tasks, particularly if the tasks will be performed by laypersons or clinicians who will interact with the given device infrequently.

Developing a Good Animation
If you have read this far, you are probably interested in more details about how to produce a good animation. Keep things simple. Ways to do that include:
• Ensure that developers have practiced good human factors engineering to ensure that the user interactions with the given device are not overcomplicated. Of course, this might not be an option if the design is frozen when the time comes to produce the animation.
• Develop a complete understanding of the user’s task so that you know exactly what needs to be demonstrated to the user.
• Produce a storyboard (i.e., a hand-drawn, visual outline) of the planned demonstration.
• Take photos of people performing the discrete steps that users must perform. Make sure that the photos are taken from the most effective angle and distance, noting that both wide-angle and close-up images have their place in an animation.
• Generate the computer drawings necessary to produce the animated sequence with “tweening” support from the animation program.
• Evaluate the resulting animation with the presumption that it needs enhancement.
• Repeat the last few development steps until the animation seems as clear as possible.
• Conduct a usability test to evaluate strengths and shortcomings in the animation’s ability to assist device users.
• Again, refine the animation based on the test results and possibly retest it. Note that validating the animation by means of usability testing might be necessary if it is cited as a mitigation against a high risk of harm arising due to user-device interactions.

You can also enhance the animation by adding “closed caption” style text below the images and/or playing a spoken voice-over at the same time the animation is playing, the latter option being a feature one might allow users to turn on or off at their discretion.

**Animation Design Tips**

Here is a short list of tips for designing animations that medical device users are likely to understand and follow:

• Present guidance in logical and small-to-medium size chunks. Accordingly, animate one main task at a time.
• Play the animation at a pace that most users will find acceptable. We find that this pace is typically 15-20% slower than the actual time it takes to perform a task. You can determine the right pace by collecting feedback on various paces from intended users who have not seen it before.
• Include brief, 2-3 second pauses after key steps to prepare viewers to notice important details.
• Use fades to create smooth transitions between distinct sections of the animation.
• An animation runtime of 15-30 seconds per distinct step is a good target, lest viewers start to forget important details.

• Start animating with enough drawings so that the level of “tweening” is appropriate. Large jumps between original drawings can make certain actions look jumpy or lacking in essential details.
• Make the drawings realistic to the point that they clearly represent the actual device, but exclude minor details that might distract from more salient ones.
• Zoom in and out to highlight important details.
• Avoid excessive motion and extraneous visual effects, which can distract from key details and overwhelm the viewer. In most cases, animate only two or three on-screen elements at one time, keeping other on-screen elements still.

**Conclusion**

All medical device users, be they laypersons or highly experienced clinicians, can use help when responding to alarm conditions, particularly those that are infrequent and complicated. Endowing a medical device with animated troubleshooting guidance provides a welcome safety net for users who might otherwise stumble when responding to an alarm. Such animations can be “tuned” to speak a layperson’s or clinician’s language, sometimes literally if you include a voice-over. Moreover, animations can be set to play automatically when an alarm occurs, or play on demand. Therefore, medical device users can expect to see a lot of animations playing on medical devices in the next five years. Some animations will be better than others based on the artistic and teaching talent brought to bear during their creation, but all are likely to be better than trying to respond effectively to “Error 43” displayed on a thumb-size screen.

**Endowing a medical device with animated troubleshooting guidance provides a welcome safety net for users who might otherwise stumble when responding to an alarm.**

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Beyond Sound:
Using Systems Integration to Advance Alarm Functionality

Dave Dyell

You could say that 2002 was a bad year for clinical alarms. That was the year that the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) (now The Joint Commission) assessed 23 reports of deaths or injuries related to long-term ventilation and determined that 15 (65%) were related to “the malfunction or misuse of an alarm or an inadequate alarm.”

No doubt, that number is sobering. But it’s also nearly a decade old. Has alarm management improved? Gotten back its good name? Not necessarily. In fact, clinical alarms have taken either first or second place for the past three years on the ECRI Institute’s annual list of Top 10 Health Technology Hazards.

The Sound Problem
Why aren’t alarms working? Mark R. Rosekind, a psychologist, member of the National Transportation Safety Board, and former operations specialist at NASA, believes he knows the answer, or at least part of it.

Rosekind has seen everyone from air traffic controllers to nuclear plant operators to astronauts ignore alarms, exhibiting what many today refer to as alarm fatigue.

“The volume of alarms desensitizes people,” Rosekind told The New York Times in August 2010.1 “They learn to ignore them. There’s so much information overload. If that alarm doesn’t have meaning for that user, that operator, they’re going to start ignoring it. It doesn’t matter what environment you’re in.” Today’s clinician operates in an alarm-heavy environment. A 2010 Critical Care Medicine piece titled, “Intensive Care Alarms—How Many Do We Need?”2 stated that 40% of all alarms do not correctly describe the patient condition and can be classified as technically false; only 15% of all alarms can be considered clinically relevant.

40% of all alarms do not correctly describe the patient condition and can be classified as technically false; only 15% of all alarms can be considered clinically relevant.
How problematic? The American College of Clinical Engineering (ACCE) Healthcare Technology Foundation surveyed 1,327 clinicians, engineers, technical staff and managers in 2004. The majority agreed or strongly agreed that nuisance alarms occur too frequently (81%); disrupt patient care (77%); and reduce trust in alarms and cause caregivers to disable them (78%).

The Good News
Clinical alarms should be useful tools for caregivers, not something they are driven to disable. And they can be. Many hospitals have dramatically reduced nuisance alarms and increased alarm utility through evaluation and inventory.

These efforts certainly go a long way in reducing alarm fatigue. But to further advance alarm systems requires a change in thinking, or a shift towards integration. As is the case in almost any organization, the integration of efforts and information enhances workflows and efficiencies. Consider the ways in which connectivity between devices, communications systems, and information systems within hospitals augments alarm systems in the following scenarios.

Scenario #1: The Perfectly Configured Alarm That No One Hears
Ideally, patients connected to medical devices such as monitors, pumps and ventilators would be confined to critical care units—units designed for high acuity. However, overcrowding in hospitals and the general trend of rising patient acuity has led to variable acuity units or environments. In these units, nurse-staffing levels are low, making medical device alarms essential.

But alarm audibility can be challenging in these makeshift spaces; large rooms, long hallways, and rooms with doors are not ideal for ensuring audibility. So what happens when a perfectly configured, clinically relevant alarm sounds behind a closed door in a room at one end of an L-shaped, variable acuity unit and the clinician is at the other end of the L?

Solution
In response to these challenges, a variety of alarm extensions have been developed. These solutions complement, or extend, the alarm when the appropriate clinician is out of range of an audible alarm. These alarm extension technologies route or channel the device alarm to a variety of systems, including nurse call systems, paging systems, enunciation systems, or cell phones via an internal, secure, wireless network.

In a similar fashion, some patient monitors have the ability to provide clinicians with information about alarms that are sounding for other patients. So when you are looking at the patient monitor for patient X and you hear an alarm sound for patient Y, you can use patient X’s monitor to view information about the alarm for patient Y.

In variable acuity settings, these alarm extension technologies benefit both clinicians and patients. Unattended alarms can greatly affect a patient’s perceived level of care, especially if that patient feels isolated behind a closed door at the end of a hallway.

It’s important to note that, if device parameters aren’t set correctly, alarm fatigue will still occur; it’s just as frustrating to receive repeated text messages about clinically irrelevant events as it is to hear alarms about them.

Scenario #2: Choosing Between Two Patients
A patient’s heart rate exceeds her predetermined threshold, and the monitor sounds an alarm. The clinician hears her alarm sounding,

Minimize Nuisance Alarms by Taking Inventory
Many hospitals have dramatically reduced nuisance alarms through evaluation and inventory. For example, The Johns Hopkins Hospital in Maryland began a pilot project in December 2005 to reduce clinical alarm fatigue. The hospital formed a task force to examine the purpose and accuracy of each alarm. Default alarm settings were adjusted to appropriate levels, and staff members underwent alarm management training.

The result? A 43% decrease in critical alarms. It should be noted that improvements of this kind demand a hospital-wide effort. Nurses alone cannot be expected to configure countless devices from countless manufacturers—especially since each device requires unique operator knowledge. Instead, hospital management must allocate the appropriate resources to the task.
but he is down the hall serving another patient in moderate need of care.

This creates a quandary for our clinician: How quickly should he respond? Should he stop serving the patient he's with to go inspect the sounding alarm that may or may not be clinically relevant? Or, should he take 30 seconds to finish what he's doing and then go check the patient?

Solution

Thanks to new technologies, clinicians can now receive a text message or email stating, “Patient X's upper threshold for heart rate has been exceeded. The current heart rate is Y.” Clearly, this kind of notification provides more context than say, an audible-only notification. The alert not only tells the clinician that a threshold has been crossed, but also, by how much. This additional description provides the clinician with the information he needs to make an informed decision about how to respond.

“If you’re an RN, and you’re in someone else’s room, and you receive an alert indicating that another patient is crashing, that’s a lot different than an alert about the CO₂ level being a little low,” says Jena Milan, product manager at device integration company iSirona. “When clinicians have an idea as to why that alarm is sounding, they can prioritize and better manage the care of both patients—the one they’re providing care to at the moment as well as the patient whose alarm is sounding.”

Scenario #3: When a Clinician Simply Cannot Respond

A respiratory therapist conducts a vent check in a surgical intensive care unit. She’s cleaning out the patient’s respiratory airways when she receives a clinically relevant, descriptive text about another patient in extreme need. She knows the alarm condition is critical. But she’s already in the middle of a critical procedure. She simply cannot stop what she’s doing.

Solution

Integrated patient care communication systems (or integration middleware systems) link communication technologies within a hospital, from nurse call stations to patient bed to clinician cell phones. Though the respiratory therapist in our scenario cannot attend to the patient whose alarm is sounding, she can forward the alert to another clinician via a lightweight badge or communication device.

These communication integration solutions are helpful for clinicians in other ways as well. It is often forgotten that, in addition to providing direct care, caregivers must also coordinate and communicate with physicians, manage processes for outgoing diagnostic tests or therapies, manage visits from outside therapists, and coordinate with social workers. Activities like these and many others must take place in between nurse calls, text messages, overhead pages and medical devices alerts. In this way, integrated communication systems are highly beneficial for clinicians.

Scenario #4: One Event Drives a Cacophony of Audible Alarms

At the point of care, a patient is connected to several medical devices, each of them performing a variety of tasks, from monitoring heart rates to the delivery of therapy. Each device has its own alarm parameters, categories and methods of annunciation.

An adverse event occurs, and the patient needs attention. Our patient’s physiological change triggers duplicate alarms in the various devices to which he or she is connected. As each device sounds off, clinicians are not given a clear message. Instead, they are overcome by flashing lights and a myriad of sounds.

“There can be so many alarms at a given time that the patient care environment becomes dysfunctional,” says William Hyman, professor with the department of biomedical engineering, at Texas A&M University. “When environments become excessively noisy, it can become so unbearable that users have been known to sabotage alarms.”

Solution

Some manufacturers have developed “smart alarms,” or alarm systems that integrate parameters from multiple, disparate devices to evaluate the validity of a single alarm. These systems are “smart” enough to emit one
alarm—instead of, say, five—per adverse event, drastically reducing the number of repeat alarms.

Do clinicians and engineers trust these smart alarms? The ACCE-led survey indicated that 80% of respondents support smart alarms. However, according to Tobey Clark, CCE, director of instrumentation and technical services and adjunct faculty member in engineering and nursing/health sciences at the University of Vermont, Burlington, smart alarms have fallen behind the curve. Clark wrote: “In general, ‘smart alarm’ technological progress has not kept pace with overall medical device advances, in part due to manufacturer reluctance—liability concerns and business factors are at the top of the list.”

Scenario #5: When Device Parameters Aren’t Enough
A patient in the ICU is having trouble breathing, and he’s on a ventilator. His respiratory therapist receives a “disconnect” ventilator alarm on her smart phone. Most likely, this is a nuisance alarm. But the therapist can’t be sure. How is she to interpret the alarm?

Solution
Ventilator disconnect alarms can be corroborated by oxygen saturation values, which come courtesy of another device. When combined, the disconnect alarm and the oxygen saturation values provide more clinical context than either could individually. Imagine if, in this scenario, the ventilator disconnect alarm was routed to the clinical information system (CIS), which was programmed to bundle the alert with real-time data about the patient’s oxygen saturation values before pushing it to the respiratory therapist.

Discussion
As demonstrated in these scenarios, advances in the areas of alarm extensions, directed notifications with context, integrated communications systems, smart alarms, and device interoperability are changing the face of alarm management. These kinds of advances are possible when, through device connectivity, hospitals are able to channel real-time data from multiple devices into the CIS.

Furthermore, with real-time data in the CIS complementing alarms, algorithms can synthesize data from multiple devices, including latency information, duration of events and frequency. This information can then interact with the patient’s medical history. The sky is the limit in this regard, though these advances face many of the regulatory and liability concerns that smart alarms do.

No doubt, the handling of device alarms in clinical environments is a sensitive issue. This is as it should be, as device alarms greatly impact patients’ lives. Alarm efficacy can be greatly enhanced through intentional device parameter setting. Additionally, new technologies and communication solutions are undoubtedly changing alarm management for the better.

Ultimately, patient safety is an industry-wide issue; so, too, is improved alarm management. When device designers, manufacturers, buyers, users, and regulatory bodies come together, alarms can be at their best—informing clinicians and protecting patients.

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Interest in third-party alarm notification systems continues to increase as clinicians work to improve alarm response and reduce adverse events in an increasingly busy and distracting patient care environment. These systems promise to unburden the clinician from the many portable devices they carry for communication and alerting purposes as well as to provide management of both alarms and clinicians. However, these systems have daunting infrastructure requirements as well as clinical workflow requirements. From a technical viewpoint, a basic understanding of the different functional components as well as required underlying infrastructure will better prepare clinical engineering professionals to assess the different vendors’ systems as well as provide for proper implementation, support, and clinical expectation management.

Communication and Paging Systems
See Figure 1 for a functional diagram of a generic third-party alarm notification system. Each of the system’s components is described in the following sections.

Signal Input Systems
There are different types of signal input systems. One is a medical device gateway, which facilitates communication with external systems such as alarm notification servers. This gateway can be supplied by a medical device vendor, a third-party medical device integration vendor (example vendors: CapsuleTech, Nuvon, iSirona) and/or a third-party alarm notification vendor. Device gateways send HL7 messages or proprietary messages to the alarm notification server. Both third-party medical device integration systems and alarm notification systems can acquire data from multiple medical device manufacturers’ devices. Lastly, a nurse call gateway aggregates nurse call information and sends a proprietary message (often using a variation of the session initiation protocol [SIP] or telocator alphanumeric input protocol [TAP] communications protocols) to an alarm notification server.

Some might argue that these input systems are basically the same; however, based on actual interfacing capability and signals gathered at some of the interfaces, these are different types
of systems. For example, a nurse call system may use a simple on/off switching and signaling mechanism which minimizes the specificity of the information that can be propagated. In another example, a medical device gateway may send a ‘snippet’ of an arrhythmia waveform with the alarm notification.

Some medical device system interfaces are capable of two-way communication, such that a clinician can remotely “silence” an alarm with acknowledgement at their communication device; usually this functionality is not implemented due to regulatory risk issues. The nurse call system interfaces are capable of two-way communication as well, such that acknowledgement by the clinician with the communication device will reset the nurse call system at the gateway and/or at the bedside annunciator.

The common data element providing context among data from various signal input systems is the patient. The association of patient identification with data from a signal input system is referred to as patient context. All of these components—both the signal input systems and the alarm notification server—must establish patient context to associate a patient with their data before sending information to the next component in the overall alarm notification system. Establishing patient context must be done by the signal input systems.

Common methods for establishing patient context include manually entering a patient’s name and identification (ID) into the signal input system, using a barcode reader to capture the patient’s name and ID, or having ADT (Admission Discharge and Transfer, a common information service available in hospital information systems) interfaces to the different gateways from which a clinician selects the patient demographic information. How patient context is established depends upon the vendors of each of the systems and how the provider configures their system at installation.

**Alarm Notification Application Server**
This server receives patient-identified information from the signal input systems. The alarm notification application server then looks up the assigned clinician for that particular patient as well as the assigned communication device for the clinician. This server may also filter an alarm by the signal input system generating the alarm because alarms from some devices, such as a ventilator or portable dialysis, may be routed to a technologist or clinician other than the patient’s assigned caregiver. It then sends messages directly to the specific communication device specified by the alarm notification application. Messages sent to wireless phones are sent via the telephony gateway.

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**Figure 1.** Block Diagram of Alarm Notification System, High-Level Functional View
Most of the alarm notification application servers have a set of “rules” which are applied to the incoming signal. These rules allow message addressing and prioritization and are customized based on customer preference. Typically, the prioritization is based on alarm severity. In addition, triage scenarios can be defined such that message receipt and acknowledgment accountability can be attained. Moreover, there are some vendors in this space who offer decision support functionality in which multiple medical device inputs are analyzed and alarms messages are generated on a set of algorithms regarding the combined physiological information. A prototypical alarm notification server architecture is depicted in Figure 2.

This sample, high-level alarm notification server architecture diagram shows the main components of the server. The software architecture of alarm notification servers is similar across manufacturers. More mature systems, such as Amcom’s CommTech Wireless solution, are mostly coded software; while more current platforms like Extension use highly configurable software “engines” for most of their functionality. All alarm notification servers include a database management system that stores data from input systems and logs all of the internal server transactions and interactions with endpoint devices and users.

In computing, an enterprise service bus (ESB) is a software architecture component that provides basic services for complex architectures via an event-driven and standards-based messaging engine, the bus. Some alarm notification systems utilize an ESB or may implement a Service Oriented Architecture (SOA) component. Systems based on SOA, such as Emergin, package server functionality as a suite of interoperable services defined by the SOA. Because SOA does not include the concept of events, systems using SOA include a separate messaging engine. The ESB or messaging engine performs message triage, routing, and escalation based on how it is configured. A rules engine may be included to provide clinical decision support in processing input system data, generating and managing messages.

A key advantage of these engine-oriented software components is that scripting rather than writing software code defines their specific use. Depending on the system’s design, technicians or trained end-user system administrators can modify message routing and escalations or the appearance or content of a display of data. The usability and accessibility of scripting and/or configuration tables is highly variable from product to product. Scripting on some systems are not suitable for, or accessible by, customer personnel.

Current best practice for software architectures is to implement features and functions as independent modules, or plug-ins. When this approach is used, a framework for supporting plug-ins is required. A web server is used for deploying client applications on endpoint devices. A relatively new addition to this kind of modular “engine” architecture is the dashboard. A patient monitoring central station display is a dashboard for patient monitors. Many healthcare IT applications also include dashboards to summarize data. By using a dashboard, manufacturers can quickly configure displays of summary data that are updated automatically by the system.

**HL7 Interface Engine**

An interface engine provides HL7 integration capabilities for ADT feeds to support patient context, and may include results reporting for receiving diagnostic reports that may generate messages.

**Telephony Gateway**

This system provides the messaging to handsets which can be via VoIP, cellular, digital
enhanced cordless telecommunications (DECT) or paging frequencies. Most telephony gateways use a version of the SIP protocol to communicate with external systems like alarm notification servers. Telephony gateway compatibility does depend upon alarm notification vendor. Telephony gateways are designed to operate with specific handsets, so compatibility depends upon the telephony gateway vendor as well. Ascom, Cisco, Polycom, Voalte and Vocera are vendors in this product space.

**Integrating System Components**

Alarm notification systems are often multi-vendor solutions by necessity. The number of vendors involved, and which vendor provides what blocks in the system diagram, is highly variable. Current examples of alarm notification solutions available from two medical device manufacturers are Welch Allyn's AcuityLink Clinician Notifier and Masimo’s Patient SafetyNet. These are effective systems, but only support the manufacturers’ medical device products. Patient-centric systems that support products from multiple medical device and nurse call manufacturers are only available as third-party solutions.

Third-party alarm notification system vendors include Amcom CommTech Wireless, Ascom Unite, Cardiopulmonary Corporation, Cerner AlertLink, Extension, GlobeStar Connexall, and Philips Emergin.

The medical device signal input system component can be provided by the medical device manufacturer, as is the case for patient monitoring network gateways and infusion pump gateways. A third-party medical device signal input system, also known as a medical device data system or MDDS, can integrate medical devices that do not include any network capability or a gateway, and are often used to implement electronic clinical documentation for electronic medical records (EMRs). Many alarm notification systems also include medical device signal input system capabilities. If medical device data acquisition requirements are only to be used to drive the alarm notification solution, the MDDS features offered by the alarm notification vendor should provide sufficient functionality and may eliminate the need for a separate MDDS vendor. When additional medical device connectivity features are desired, such as pushing data for clinical documentation in the EMR, the MDDS features provided by an alarm notification vendor may be inadequate and should be validated as suitable for both messaging and clinical documentation applications.

Any interface is made up of two halves. For example, nurse call integration is provided by an interface or application programming interface (API) in both the nurse call system and alarm notification system. Both vendors may sell their side of the interface as a gateway, or offer the interface as an option on another generalized system component. Currently, there are no third-party gateway manufacturers that handle the signal input system side of an interface.

Because no standards are used, signal input system vendors must actively participate in and support the integration of their products with any third-party system, including alarm notification systems. The availability of interfaces between alarm notification system vendors and third-party medical device and system vendors is highly variable. The availability of interfaces should be a key factor in vendor selection.

As mentioned earlier, patient data moving through the alarm notification system must be identified with the correct patient, and should be established in the system closest to the patient—ideally at the patient’s bedside. When a third party provides the MDDS, patient context must be established in that system before data is passed to the alarm notification server. If the alarm notification vendor provides the MDDS, the alarm notification solution provides the patient context function.

The scenario where a third-party MDDS passes patient data associated with a physical location rather than a patient identity is not best practice. Patients sometimes change their location frequently during an inpatient episode, and systems tracking patient location can be out of sync with the patient’s actual location.

*When additional medical device connectivity features are desired, such as pushing data for clinical documentation in the EMR, the MDDS features provided by an alarm notification vendor may be inadequate and should be validated as suitable for both messaging and clinical documentation applications.*
and can result in misidentification of the patient. When patient location is used, the alarm notification system must associate a patient with that location. This approach introduces an unnecessary level of abstraction that can result in a misidentified patient.

**Availability of Interfaces**

As noted earlier, the availability of interfaces between system components is a key purchase criterion for the components that encompass an alarm notification system. Interfaces to medical device systems are especially limited. Nurse call system interfaces are also somewhat limited. Unlike medical device and nurse call manufacturers, whose “open” interfaces require approval from the company (which is often withheld), and signed non-disclosure (NDA) and license agreements, most telephony gateway interfaces are truly open. One can go to the telephony manufacturer’s public website and download all required documentation in a software developer’s kit; there are no NDAs or license agreements to sign. Engineering support is also available from telephony gateway vendors for a modest cost.

Selecting an alarm notification solution that does not have all the complete and operational interfaces required for a specific deployment is problematic. Should the input system vendor (typically medical device or nurse call) be unwilling to work with the alarm notification system vendor to create the necessary interfaces, it is up to the system purchaser to attempt to create sufficient incentive for the recalcitrant vendor to support an interface development effort. Creating such interfaces may result in additional charges for the purchaser from the input system vendor, alarm notification vendor, or both. Worst case, the input system vendor refuses to cooperate in the development of a needed interface, and another alarm notification vendor must be selected.

The preferred method for making disparate systems interoperable, as between signal input systems and alarm notification systems, is through industry standards. The organization Integrating the Healthcare Enterprise (IHE, www.ihe.net) was created to facilitate test and certification of standards based integration between disparate systems. The IHE has made considerable contributions to the industry in diagnostic imaging and cardiology, markets where manufacturers have widely adopted industry standards. In 2005, the IHE created a new domain, Patient Care Devices (IHE-PCD) to foster similar standards-based interoperability among common medical devices and systems found at the point of care. Because manufacturers in the PCD market have not adopted standards, the work of the IHE-PCD has been difficult and slow. The IHE-PCD has defined an alarm communication management (ACM) profile.¹

As of this writing, only two manufacturers have published conformance statements with the ACM profile on the IHE product registry site (http://product-registry.ihe.net/PR/home.seam). Presently, it is not possible for a provider to purchase an alarm notification system based on the ACM profile. Providers are encouraged to push manufacturers to support standards, and to achieve approved integration statements from IHE. But ultimately, hospitals cannot buy a standards-based alarm notification system that is tested and certified by IHE because none yet exist.

**Communication Devices**

Communication devices can be general-purpose computers running client software on desks or carts, personal data assistants (PDAs), tablet computers, smart phones, or VoIP handsets. These devices can be broken down into those suitable for stationary or portable use (desktop computers and computers or tablets mounted on carts) and mobile devices carried by clinicians (PDAs, handsets and some tablets). Communications can also be divided into two groups, closed-loop two-way messaging, and open-loop one-way messaging.

Most contemporary devices provide two-way communications with message receipt and possibly responses or end user messaging back to the alarm notification system. One-way devices merely receive the alerting message and function similarly to a pager. A limitation of one-way devices is that the alarm notification server has no way to verify if the communications device or the user has received a message. Two-way devices may allow for other types of
communication: text messaging, voice messaging, and access to email and other services, assuming the functionality has been enabled.

Communication devices can use paging frequencies, shared or dedicated wireless frequencies, or even cellular frequencies. Currently the majority of communication devices operate on Wi-Fi networks. Communication device functionality can also vary due to more vertically integrated product offerings using proprietary mechanisms across the data communications path. For example, one can buy an Ascom middleware solution along with Ascom handsets and the resulting functionality of the handset with regards to types of messages received at the handset can be “richer” compared the use of the Ascom middleware solution with another vendor’s communication device. Similarly, some systems (like the system from Voalte) enable rich communications using iPhones and iPod Touch devices, devices that are not currently supported by enterprise telephony systems.

Infrastructure
All of these alarm notification systems—and their related signal input and access to communications devices—rely upon the enterprise network infrastructure which provides means for sending messages throughout the integrated system. Cisco, Meru, and Aruba are vendors in this product space. Some network manufacturers also offer telephony systems, and some do not. Depending on the frequency used for signal propagation to the handsets, the vendor chosen for the messaging/middleware solution, wireless network infrastructure, and communication devices may be the same. This vertical integration can be beneficial in providing tight coupling and signal propagation; however, it also may lead to incompatibilities with other system-alerting products.

The servers and core network used to deploy an alarm notification solution should use redundant and high-availability configurations in order to minimize unscheduled down time. The end-to-end system, from point-of-care medical devices to wiring closets and server farms, should have appropriate backup power supplies, cooling and ventilation, and physically controlled access. Life-critical system components should be clearly labeled as such, with color coding for network cable runs and patch panel cabling. Many providers have policies and procedures covering these topics for patient monitoring systems and other life-critical medical device systems. These policies and procedures should be extended to alarm notification solutions, especially if the system is being used for applications such as medical device alarm notification and/or critical test results management.

A meaningful level of testing is required to ensure that changes and upgrades to infrastructure do not introduce latent defects in the operation of the overall alarm notification system that could result in failure. Most provider test labs are limited to a very small selection of network and other systems. Proper testing for an alarm notification system, or any networked medical device system, includes the use of an end-to-end test system, including a selection of medical devices and simulators to generate test data that represent the actual enterprise network environment. Wireless network infrastructure should include at least a couple of controllers and a half dozen access points. Subsequent to a successful test in the lab, network upgrades should be deployed in phases, starting with the least complex and demanding environments. Over three or four phases, the deployment of network upgrades should be extended into more demanding network environments. As many hospitals have learned, jumping from a very limited test lab to house-wide deployment is a recipe for disaster.

Alarm notification systems are typically installed in an IT infrastructure that meets the alarm notification manufacturer’s specifications. These specifications often include wired and wireless networks, computer hardware and system software, and the physical operating environments of infrastructure equipment. Providers may chose to not meet certain infrastructure specifications, but manufacturers are likely to require providers to sign an agreement stipulating that the provider understands they are assuming responsibility for modifying a regulated medical device.
As providers and industry begin to enter a period of increasing levels of systems integration and eventually interoperability with medical devices, it is important to follow practices that will ensure sufficient levels of patient safety and system effectiveness.

### Governance and Regulatory Considerations

Alarm notification systems rely upon an institution’s information technology infrastructure for communications. To ensure the continued safe and effective operation of alarm notification systems, it is the opinion of these authors that the IT governance in most hospitals must be enhanced. This need impacts biomedical and clinical engineering because they are the best resource to provide an appropriate life-critical perspective to what is currently a mission-critical IT perspective. How documents are controlled, risk management, change management, configuration control, and verification testing are often the IT operational areas most in need of revision. Providers deploying alarm notification systems are advised to adopt a risk management process as described in IEC 80001\(^2\) or ISO 14971.\(^3\)

Unfortunately, there are no industry standards providers can adopt to guide them in defining and implementing the kinds of IT governance enhancements that are required for life-critical applications. Industry best practices are just now emerging in this new level of IT governance.

Alarm notification systems are regulated medical devices that are designated Class II in risk and require FDA clearance prior to sale (via the 510(k) process). FDA has exercised limited regulatory discretion toward alarm notification system manufacturers, i.e., not pursued enforcement actions provided they refrain from displaying physiological waveforms. Some alarm notification solutions are FDA-cleared medical devices (e.g., Cardiopulmonary Corporation’s Bernoulli system), and FDA has recently signaled that manufacturers without FDA clearance may face enforcement action in the near future.\(^4\) Providers should determine an alarm notification manufacturer’s regulatory status. A quick search of the FDA’s 510(k) database can accomplish this, or alternatively providers can request documentation, e.g., a copy of the FDA 510(k) clearance letter, from the manufacturer. Manufacturers without clearance should not necessarily be excluded from consideration provided they are pursuing a path to bring them into regulatory compliance in a timely period. The FDA rarely pursues enforcement actions that would be unduly disruptive to providers, especially against manufacturers that are actively engaged with FDA and making progress towards compliance that is acceptable to FDA. Providers should be warned that in the event the FDA pursues enforcement actions against a manufacturer without clearance, the manufacturer could be forced to recall their alarm notification systems from customers.

Enterprise IT infrastructure is made up of products with relatively short product life cycles. New software releases and hardware obsolescence necessitate frequent verification and validation testing by the medical device and alarm notification system manufacturers before it can be safely deployed in customer sites. Providers must allow the manufacturers of medical devices, including the alarm notification system, to complete verification testing prior to installing IT upgrades. Providers that modify IT infrastructure that makes up part of a medical device system, without the medical device manufacturer’s approval, are modifying a regulated medical device and may bear additional liability as a result.

As providers and industry begin to enter a period of increasing levels of systems integration and eventually interoperability with medical devices, it is important to follow practices that will ensure sufficient levels of patient safety and system effectiveness. The evaluation and selection of alarm notification systems is a process of discovery, starting with a thorough needs assessment and in-depth understanding of the prospective alarm notification solutions.

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### References


The earliest human alarm systems appear to have been deployed at Pinnacle Point on the south coast of South Africa between 135,000 and 175,000 years ago.\textsuperscript{1,2} Ochre dye signs cautioned of dangers on the way to food supplies.

Patient monitoring systems are deployed to optimize the workload of trained medical personnel; many of the tasks they once performed have been reallocated to machines. But patient monitoring systems are, in general, inadequately designed. The alarms produce both caregiver and patient alarm fatigue. Far too many false alarms bedevil us. Alarm systems should instruct and not alarm.

For the last century the problem of medical alarm systems support of high technology has been the subject of numerous publications.\textsuperscript{3-8} The causes of the lack of progress in the sophistication of medical alarm systems are multifactorial:

1. Standards for alarm systems should never be set by narrowly based committees. For instance, standards development progress has been indirectly compromised by the lack of clinicians and lack of clinical control of specifications for deployed alarm systems.

2. At many medical research university hospitals, the distributed alarm systems for research laboratories are more advanced than the systems for patients.

3. Too often, alarm systems are not intelligently agreed upon between different departments among which patients are transferred during their hospital stays.

4. With 80\% of U.S. surgical operations carried out without admission to hospital, the requirement for distributed alarm systems in home care is essential, but is only being met in housing that is being specially modified.

5. The relationship between civil authorities and home care distributed alarm systems is still fragmented and rudimentary. Police, fire protection authorities, and providers of electric power and other utilities for domestic use should be informed of the deployment of high-tech medical equipment within patients’ homes and nursing homes.

6. The advances in burglar alarm systems including voice transmission of information are often superior to those in hospital alarm systems.

7. Privacy and confidentiality concerns for alarm systems vary by country.

8. The policy for utilization of batteries in motor vehicles for support of home care equipment should be further refined and standardized.

9. The number of deaths caused by alarm system fatigue of the caregiver should be more closely investigated, as should the

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**About the Author**

The following is my list of safety and performance requirements for medical alarm systems in the 21st century:

1. Alarm systems shall not alarm either patient or caregiver.
2. Medium- and low-priority alarm signals should be informative; so, ideally, should high priority.
3. Alarm systems shall readily distinguish between serious deterioration of the patient and malfunction or failure of equipment.
4. Distributed alarm systems should be able to escalate in an intelligent and predetermined manner.
5. The time of response to the alarm system by the designated caregiver should be retrievable.
6. The rate of escalation of the alarm system should be retrievable.
7. Alarm-setting limits shall be discussed for each individual patient, with review and possible adjustment at least daily.
8. Equipment for life support and for patient monitoring shall have an identifiable alarm system, the data of which are retrievable.
9. The dissemination of an alarm system shall take into account the exact location of back-up equipment.
10. For each piece of life support equipment including infusion pumps, the totality of alarm system activation shall be retrievable between each designated service interval.
11. The regular assessment of the distributed and escalating alarm system function complexities and designated personnel shall be reviewed at an agreed preset interval.
12. The requirements listed above and their fulfillment and practice shall be agreed by the chiefs of services involved and shall be agreed with the chief executive officer of the medical institution and available for presentation to trustees and regulatory authorities.

References


Medical Device Alarms Summit

October 4–5, 2011, Herndon, VA  (near Washington, DC’s Dulles Airport)

You are invited to play an active role in a multi-disciplinary “all hands on deck” summit of medical device industry representatives, clinicians, clinical engineers and technicians, academics, patient safety officers, subject experts, and other stakeholders. Following the model of the successful 2010 AAMI-FDA Infusion Device Summit, stakeholders will develop priorities on the key issues with the safety and effectiveness of medical device/system alarms. The event will be jointly convened by AAMI, ACCE and ECRI Institute.

Over a recent four-year period, the U.S. Food and Drug Administration reportedly received more than 500 reports of patient deaths related to alarms on monitoring devices. The topic has been the focus of national media attention, a Joint Commission sentinel alert, a special ECRI Institute report, a special AAMI issue of Horizons (May 2011), and peer-reviewed articles from all three conveners plus many other organizations. Alarm safety was one of the top issues in recent AAMI and ECRI Institute surveys on “top 10” device issues.

Your input is essential to this effort, and we look forward to working with you on October 4-5. For complete details, visit www.aami.org/alarms.

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