

# Safety Innovations

## Recommendations for Alarm Signal Standardization And More Innovation

### The Christiana Care Health System Experience

Christiana Care developed a system-wide alarm policy and protocols that defined its alarm management strategy for alarmed medical equipment, including flex monitors, standard cardiac monitors, pulse oximeters, and infusion pumps.

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## About the Healthcare Technology Safety Institute (HTSI)

Founded within the AAMI Foundation, the 501(c)(3) charitable arm of AAMI, HTSI is a community of leaders throughout the healthcare system that are dedicated to one common vision, "No patient will be harmed by healthcare technology."

HTSI's mission is "To engage the entire healthcare community in multi-disciplinary safety initiatives that strengthen the development, management, and use of healthcare technology for improved patient outcomes." HTSI engages the healthcare community in research, education, consensus, and partnerships related to the challenges facing healthcare technology industries, regulatory and accrediting bodies, clinicians, caregivers, and patients.

## ALARM CONDITION

*State of the ALARM SYSTEM when it has determined that a potential or actual HAZARDOUS situation exists for which OPERATOR awareness or response is required.*

*NOTE 1 An ALARM CONDITION can be invalid, i.e. a FALSE POSITIVE ALARM CONDITION.*

*NOTE 2 An ALARM CONDITION can be missed, i.e. a FALSE NEGATIVE ALARM CONDITION.*

## ALARM SIGNAL

*Type of signal generated by the ALARM SYSTEM to indicate the presence (or occurrence) of an ALARM CONDITION*

*From IEC 60601-1-8:2006+A1:2012, 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*

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*This paper is based on the real life experience of one organization that has learned from its experiences. Healthcare organizations are unique, and each integration involves potential other barriers and challenges that cannot possibly be anticipated here. A thorough, organization-specific and multi-disciplinary risk assessment is an essential foundation for success. Recommendations and tips in this paper will help support that assessment but cannot take the place of it.*

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# Recommendations for Alarm Signal Standardization and More Innovation

**Martha Vockley**

## At a Glance

**Subject:** Christiana Care Health System

**Size:** Two-hospital system includes 913-bed Christiana Hospital in Newark, DE, and 241-bed Hospital in Wilmington, DE, plus outpatient facilities and services

## Introduction

Christiana Care Health System didn't set out to solve an alarm system management problem. An initial challenge that the Delaware system faced was more mundane—a shortage of beds with bedside monitors. Very quickly, though, patient safety leaders realized that this challenge was indicative of an inadequate monitoring system. A targeted effort to address that challenge turned into an ambitious, five-year implementation of a flexible telemetry monitoring system including standardized alarm systems. At the time, the initiative was “revolutionary” in scope—and it still inspires the healthcare community. Today, Christiana Care is using its alarm system, now “entrenched in the marrow and fiber” of the healthcare institution, to support more groundbreaking work.

## The Challenge

Until 1999, Christiana Care operated a traditional monitoring system, with regional telemetry beds and step-down units with bedside monitors for patients who needed cardiac monitoring outside of intensive care units (ICUs). The problem was, there weren't enough beds equipped with monitoring devices. That meant patients sometimes waited for hours for a bed.

“We had a huge problem with patients backing up in the emergency room waiting for these traditional step-down beds to open up,” says Marc T. Zubrow, MD, FAAP, FCCP, FCCM, director of critical care medicine. “Pretty much every morning, I was getting a call: ‘Everything's your fault, you've got to do something.’”

Zubrow and a multidisciplinary task force evaluated the situation and decided that Christiana Care needed a flexible telemetry monitoring system, one in which any patient in any bed could be monitored with a wireless device. “It sounds so obvious now,” he says. “It was not obvious to a lot of healthcare providers when it was first proposed. It was a huge leap for them.”

The full magnitude of implementing a new monitoring system became clear as investigation of existing practices began. “We had isolated silos of monitoring on different units on step-downs, or what they were calling tele-units at the time, for outside of the ICU,” says Maureen Seckel, APN, ACNS-BC, CCNS, CCRN, a clinical nurse specialist on the task force who now works in medical pulmonary critical care. “There were actually different monitoring systems on different units. Some nurses were assigned to stay at the monitors and review the alarm conditions while others were busy on the unit and nowhere near

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## Food for Thought

Is your hospital dealing with challenges that may be symptomatic of an inadequate alarm or monitoring system?

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the desk, so people were responding in all sorts of different fashions on different units. There were also issues and problems with patients being transferred all over the institution, which created bed flow issues. So if an elderly person broke a hip and should be on the orthopedic floor, they were then moved to the floor that had ‘tele’ and took care of patients who had, say, heart attacks. So their heart attack care may have been excellent but they weren’t getting the orthopedic care because they didn’t have that expertise on that floor. So there were a lot of bed flow issues, along with different equipment, different alarm systems, and people responding to alarm conditions and signals differently.”

“It turns out that staff on every floor was deciding what alarm conditions they wanted to respond to,” Zubrow says. Clinicians played by “different sets of rules” when it came to alarm settings and what alarm conditions were being responded to from one unit to another. “And that to me was ridiculous because no doctor could be assured that his or her patient was getting the same standard of care—it was dependent on location more than science. I felt that was just dangerous. Everybody thought that was dangerous. That made us look into the standardization of alarm conditions and signals.”

“It was a shared responsibility of all the nurses to respond to alarm conditions,” says Alan Lipschultz, CCE, PE, CSP, president of HealthCare Technology Consulting LLC and a member of AAMI’s Alarm Management Working Group. “Alarm conditions were broken up into one-star, two-star, and three-star, where three-star is the most critical. Nurses freely acknowledged that they ignored everything that was one-star and two-star.” Lipschultz was the director of clinical engineering (CE) at Christiana Care until June of 2011 and served on the task force Zubrow headed.

Two patient deaths during this period, which occurred when alarm conditions on patients being monitored for arrhythmia were ‘missed’, underscored the commitment to focus on alarm systems, Lipschultz says. In those cases, low-level alarm

conditions had signaled low-battery and leads-off situations, not clinical events.

“In both cases, it wasn’t that a patient’s death was a cause of ignoring a low battery or a leads-off alarm condition,” Lipschultz said. “In both cases, the patient was in ‘do not resuscitate’ mode, where we probably wouldn’t have done anything anyway. But if you’re responsible for knowing what’s going on with a patient, you want to know when something like that happens.” The events were a wake-up call for Christiana Care, as similar events have been at other healthcare systems.

## RECOMMENDATIONS

**Understand how caregivers/nurses are responding to alarm conditions and signals**

**Assess the care environment and alarm conditions by isolating monitoring silos.**

At Christiana Care, the conditions were:

- There were different monitoring systems on different units leading to haphazard approaches to alarm system management.
- Nurses were responding to alarm conditions and signals in inconsistent ways from unit to unit, creating workflow challenges.
- Patient transfers from unit to unit created bed flow challenges.
- Clinicians were playing by “different sets of rules” with alarm parameters from one unit to another.
- Low-level alarm signals indicated low-battery and disconnected leads rather than clinical events.

## The Monitoring Solution

Christiana Care originally had envisioned and begun implementing a flexible telemetry monitoring system configured traditionally for that time, with portable wireless devices in which alarm signals sounded locally at nurses' stations on units. But the haphazard approach to alarm management throughout the system (highlighted in more detail below) spurred the development of a task force that advocated for a more innovative approach—dedicated monitor technicians who would watch monitors remotely and notify nurses only of true positive alarm conditions. Realizing this vision challenged every major player at Christiana Care to rethink long-held assumptions, it was important to shake up healthcare practices and trust technology to perform a mission-critical function. This vision turned into the most collaborative project the system had ever undertaken.

Gaining buy-in for a system that was a radical departure from established practices required taking the medical and patient safety case to the system's hierarchy—including the chair of medicine and the CEO—and the business case for major funding to the finance committee of the board of directors. "One of the major goals of the hospital was to become a cardiac center of excellence," Zubrow says. "I said, 'This is going to be the cost of doing business. If you want to keep bringing in cardiac patients, you're going to have to be able to accommodate their needs in a rapid fashion.'" The committee approved the funding.

At Christiana Care, as in many healthcare facilities, the cardiology department traditionally 'owned' the telemetry system, since cardiac patients were most typically monitored for abnormalities. Thus, getting cardiologists on board was critical. Some were enthusiastic from the get-go; others were skeptical. In the end, in meetings and sidebar conversations where he argued that patients would be safer and physicians would rest easier with improved monitoring, Zubrow secured the approval of the cardiology department. He made the same

rounds to surgical and medical intensivists, with the same results.

To inform their planning, task force members visited several other healthcare systems that were using flexible telemetry monitoring. The task force also evaluated different vendors, ultimately switching to a company that at that time marketed the only ambulatory ECG rhythm monitor that could meet Christiana Care's wired and wireless infrastructure specifications.

"This is a device that gets strapped to the patient's chest so they can walk around with it and that, we thought, was hugely advantageous," Zubrow says. "From a patient safety perspective, if, let's say, the network goes down, we can still walk into the patient's room and push a button and see what their rhythm is. It added a definite comfort level to the clinicians and also to me as the medical director that there was a little bit of a backup. It was a technology leap in those days. Nowadays, it's ho-hum."

The early and ongoing involvement of clinical engineering and IT departments made the technology leap possible. "This is where clinical engineering and even our IT infrastructure was key," Zubrow says. "This was almost for sure the first time that we were creating a clinical system that was mission-critical. That sounds melodramatic, but if you think of it, most clinical systems that go into a hospital, if they don't work, you just go back to paper or some traditional way of doing things. But we were making a commitment that we were going to use the hospital's wireless network to provide mission-critical monitoring for the patients. That was totally new. Before that, the IT guys would say, 'We'll get to it in the morning.' This was a whole new process for them as well as everybody else. There was a phenomenal amount of discussion with regard to strategy and for the most effective, safest way to do things. It truly was an institution-wide program where we had to make sure the wireless system was robust enough to handle it."

That took some finessing. "One of our requirements when we selected the product was that it be able to run on our existing and planned infrastructure," rather than on

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### Food for Thought

What is the comfort level of your clinicians that alarm signals are being addressed?

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*"We were making a commitment that we were going to use the hospital's wireless network to provide mission-critical monitoring for the patients."*

—Marc T. Zubrow, M.D.

a separate network, says Christiana Care's Melody Kasprzak, Ph.D., project manager, information technology. "In any wireless infrastructure, you have to make sure there are no dead spots. We also wanted to make sure that every spot could be covered by two access points, so if one failed, we did not have any spots that were not covered."

Early testing and troubleshooting by both the vendor, to make sure the hardware was communicating to the right access points, and the IT network team, to make sure the access points were located optimally, ironed out these problems. "Dropout [of the communication signals and monitor functions] was the single biggest problem for clinicians for a while," Kasprzak says.

"You can test all you want, but until you actually get the load, there are things you don't find out."

The task force originally envisioned implementing flexible telemetry monitoring for the department of medicine, which comprises about 60 percent of the patient population. But it proved so popular in cardiology and medical-surgical units that it expanded to orthopedics and rehabilitation units and then system-wide. It took five years to complete, with multiple upgrades to the IT wireless infrastructure and several rounds of funding.

Today, Christiana Hospital has one of the largest installations of Welch-Allen wireless telemetry monitoring systems, Kasprzak says. The system runs on two virtual local area networks (VLANs), with 400 devices, including Micropaq® patient monitors, workstations for monitor technicians and clinicians, and servers for data collection and analysis. Initially, the system ran on the 2.4 GHz (802.11) band. With more wireless devices in use today, medical devices like telemetry now operate on the 5 GHz (802.11a) band and other wireless devices on the 2.4 GHz (802.11b/g) band.

Flexible telemetry monitoring is now embedded in the Christiana Care culture. "This is part of us," Zubrow says.

## RECOMMENDATIONS

### Commit to solving the problem:

- Realize that alarm system management is a medical and patient safety issue.
- Develop a task force that can advocate for a strategic approach to alarm system management and include physicians, nurses, clinical engineers, and IT experts.
- Involve the facility's management and hierarchy in the strategy—include the chair of medicine, the CEO, and CFO.
- Identify the departments that have the greatest interest or influence and need to get-on-board with the strategy, such as cardiology and ICU.
- Develop a business case for funding the strategy and the solution.
- Seek out, visit, or consult with other healthcare systems to glean lessons learned about alarm systems, technologies, policies, protocols, and vendors.

### Test and evaluate the technology: The Christiana Care Alarms System Task Force:

- Used the hospital's wireless network to provide mission-critical patient monitoring.
- Evaluated the wireless system to assure that it was robust enough to handle a new system.
- Assured that every "spot" in Christiana Care's facilities were covered—no dead spots.
- Tested the technology early by both the vendor and the IT department to assure that issues with hardware and access points were fully addressed.

*"In any wireless infrastructure, you have to make sure there are no dead spots. We also wanted to make sure that every spot could be covered by two access points, so if one failed, we did not have any spots that were not covered."*

—Melody Kasprzak

## The Alarm Standardization Solution

Christiana Care planned the rollout of the flex monitoring system carefully, unit by unit. Early on, the task force discovered a big, unanticipated problem—idiosyncrasies in cardiac alarm parameters, settings, and responses in different units. “It became obvious to me that it would be impossible to run a system like we had constructed without standardization of alarm conditions,” Zubrow says.

This discovery took the task force on a major, unplanned side journey that was integrally connected to its telemetry monitoring initiative. That entailed negotiating with cardiologists to agree on the PVCs (premature ventricular complexes or contractions) per minute and heart rates that were clinically significant, and similar negotiations with other physicians who occasionally used alarmed cardiac monitors.

“We actually looked at every single alarm system and alarm condition, then standardized them so that reasonable and meaningful alarm signals were going off,” Seckel says. “That sounds very simple, but it really wasn’t. It was probably a little bit revolutionary for its time because this happened between 1999 and 2000. Alarm conditions on every cardiac monitor at Christiana Care now have the same standard.”

Alarm standardization eventually expanded to include virtually all alarmed medical devices, in response to a 2005 National Patient Safety Goal from The Joint Commission to improve the effectiveness of clinical alarm systems. “We went down the list, alarm condition by alarm condition, and the electrophysiologists said, ‘We want all of those alarm conditions,’” Lipschultz says. “Marc [Zubrow] was really good about saying, ‘Do you really want to be awakened by a nurse in the middle of the night to tell you we had this alarm signal?’” That question helped clinicians concentrate on a core list of clinically significant conditions that should set off a true alarm signal.

Christiana Care developed a system-wide alarm policy and set of protocols that defined its alarm management strategy for

alarmed medical equipment, including flex monitors, standard cardiac monitors, pulse oximeters, and infusion pumps. The CE department serves as a clearinghouse that keeps the policy in effect. Biomedical technology professionals set up alarmed devices with the healthcare system’s alarm settings, rather than the manufacturers’ default alarm settings. They make sure these settings are maintained after a device is returned from servicing from the manufacturer or an external service provider. They step in if a clinician wants to deviate from the agreed-upon standards and they coordinate and document decisions and changes to the standards. The CE and IT departments also collaborate to decide which team of experts responds to any issues with specific alarmed devices.

Nurses were an essential part of the entire telemetry monitoring and alarm standardization initiative as well, with Seckel on the task force and direct-care or bedside nurses involved throughout. “All along I had nursing on board with the program to tell me what was reasonable from their point of view,” Zubrow says. “If nursing did not feel that whatever I was negotiating was reasonable, safe, tenable, that was a hard stop and we sat down and rethought it. It was an iterative, totally collaborative process.”

*“If nursing did not feel that whatever I was negotiating was reasonable, safe, and tenable, that was a hard stop and we sat down and rethought it. It was an iterative, totally collaborative process.”*

—Marc T. Zubrow, M.D.

In all cases below, manufacturer (Phillips) default monitor alarm settings are given first, followed by new default settings used at Christiana Care more than 10 years ago with no adverse change in outcomes. Similar setting changes may be done with monitors from other manufacturers.

- Default V-TACH value  $\geq 5$  PVCs. Christiana Care changed to  $\geq 10$  PVCs.
- RUN PVCS, PAIR PVCS, R-on-T PVC, Ventricular Bigeminy, Ventricular Trigeminy & Multiform PVCS — In all cases, Default ON. Christiana Care turned OFF.
- IRREGULAR HR — ON, but nurse may turn off if patient currently in atrial fibrillation.

## RECOMMENDATIONS

### Standardize alarm conditions, signals, and settings

- Involve clinicians in the standardization development process.
- Develop a core list of clinically significant conditions that set off a true alarm signal.
- Develop a system-wide alarm system policy and protocols that define an alarm management strategy for medical equipment.

### Call upon your clinical engineering or biomedical equipment department to:

- Serve as a clearinghouse that keeps the policy in effect.
- Install and set up alarmed devices with the healthcare system's alarm settings rather than the manufacturers' default settings.
- Assure that settings are maintained after a device is returned from servicing from the manufacturer or an external service provider.
- Help clinicians from deviating from the agreed-upon standards.
- Coordinate and document decisions and changes to the standards.
- Collaborate with unit staff on the team of experts that will respond to issues according to specific alarmed devices.

## The Results

A validation study (reference 3 on page 10) of the five-year implementation found that remote telemetry monitoring is “absolutely” as effective as traditional telemetry, Zubrow says. Other results include:

- **Improved patient safety and environment of care.** Standardization of alarm settings and responses resulted in an improved safety environment for patients and staff. A two-tiered phone system staffed by trained and trusted monitoring technicians was put in place. Alarm signals that indicate non-fatal or low-risk conditions are sent to a charge nurse or delegated ‘tele’ nurse on a special phone. Alarm signals indicating a fatal or high risk condition have a distinct sound or “ring” and are sent to other special phones,

placed consistently on every unit. “Previously, the nurse would have gone to the station when she heard the alarm signal to look at what was alarming and then go to find the patient,” Seckel says. “This way we go directly right to the patient.” Plus, the auditory alarm signals indicating less lethal alarm conditions are silent. “We got rid of the noise,” she says.

“What we found out is that there were side benefits, namely that it was a much quieter place once we got rid of all those alarm signals and conditions that were clinically insignificant,” Lipschultz adds. “Patients were sleeping better. Patient satisfaction was higher and nursing satisfaction was higher because they didn’t have to deal with all of those alarm signals. They knew when they were getting something real.”

- **Shared sense of responsibility and more support for nurses.** For added peace of mind, the task force made a “conscious decision that we did not want to use a wireless device for the urgent phone messages, which we call the ‘heart phone,’” Lipschultz says. “We wanted a very reliable land-line phone that was a party line. It rings on three or four locations on a unit. Everybody knows, ‘Oh, it’s the red (heart) phone ringing,’ and everybody goes running. If two people pick it up, it is a party line with everybody getting the same information. It became everyone’s responsibility.” In addition, nurses get more support from the system and from monitoring technicians in dealing with the patient conditions that set off the alarm signals. They don’t have to spend time diagnosing a full arrhythmia readout, for example. Rather, they get an abbreviated readout of the specific problem and a course of action for that problem, Lipschultz says.
- **Improved bed flow.** The initiatives had the intended effect of improving patient flow to the units most suitable to their conditions and care requirements. “You didn’t have to wait for telemetry beds to open up faster, you just put the monitor



on them and moved them within the hospital,” Zubrow says. “If you think back 10 or 12 years ago, people didn’t talk about the safety of getting patients out of the emergency room. That is recently starting to come out. For example, a critically ill patient, the longer they stay in the emergency room, the worse their outcome. Twelve years ago, people weren’t talking about that.”

## Where We Are Now

Today, Christiana Care is examining the data it gets from telemonitoring to research early warning indicators that detect an adverse event before it happens. “We looked at the 10 minutes of rhythms leading up to an event for patients that coded,” Zubrow says. “We can do that with this kind of system. We discovered, and it

### Take-away Points from the Christiana Care Experience

- The steps and approach that Christiana Care took to its alarm management system are applicable to all healthcare institutions that care for adult patients.
- Independent of the central monitoring portion of Christiana Care’s experience, this alarm system solution has applicability in ICU, ED, PACU and in units with telemetry monitoring systems.
- Institutions can implement Christiana Care’s alarm system solution or take a similar approach to alarm system management relatively rapidly once they involve the right decision makers.
  - Nursing is the key stakeholder, but physician involvement is essential.
  - If an alarm condition is not actionable, it should not be “on.”
  - Even if an alarm default setting is “off,” it can still be turned “on” for a specific patient.
- The risks of doing nothing regarding physiologic alarm settings are significant.
  - Multiple articles have pointed out the hazards of alarm fatigue.
- Christiana Care’s solution or its approach to alarm system management does not require capital investment. It can even be applied to older-generation cardiac monitors.
- Manufacturer alarm default settings for arrhythmia alarm conditions (particularly in older monitors) include alarm signals for arrhythmias that are no longer considered clinically significant.
- Standardization is important within an institution:
  - Clinical staff work in several clinical units and on varying scheduled shifts.
  - Clinicians need to know what to expect from an alarm system.
  - Prevent over monitoring on one unit versus under monitoring on another.

Healthcare organizations are unique, and it is essential for each organization to conduct a thorough, organization-specific and multi-disciplinary risk assessment before making decisions on alarm policies or alarm settings. These tips will help support the assessment but cannot take the place of a facility’s unique assessment.

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### Food for Thought

Is your facility’s device alarm system helping your clinicians perform better?

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actually matched the hypothesis, that a vast majority of the patients that code are actually not having traditional v-tach, v-fib code like you would think from the American Heart Association. They're having bradycardic arrest, which means they probably had different underlying pathophysiologic conditions." (V-tach, or ventricular tachycardia, is a regular, faster-than-normal heart rate that begins the heart's lower chambers. V-fib, or ventricular fibrillation, is a severely abnormal heart rate that can be life threatening. Bradycardia is a slow heart rate.)

"It turns out that cardiologists have gotten so good at treating coronary ischemia [insufficient blood going through the coronary arteries] that the significant percentage—if not the majority of our patients that we're monitoring—in fact are not for coronary problems," he says. "They may have a variety of other medical problems. So, the whole thrust of telemetry needs to be different. Telemetry is not just about finding v-tach, v-fib, it's about finding patients who are at risk of dying from whatever cause."

Whatever those early warning indicators turn out to be—oxygen saturation, respiratory rate, or some other indicators—Christiana Care is working to identify them, monitor them and set a standard for saving lives.

### For Further Reading

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2. Lipschultz, A. (2011). "Clinical Alarms." Presentation at the AAMI Annual Conference.
3. Zubrow, M.T., Ellicott, A.C., & Seckel, M.A. (2006). "Prospective Safety Evaluation of Traditional vs. Flexible Telemetry." AHA 7th Scientific Forum on Quality of Care and Outcomes Research in Cardiovascular Disease and Stroke. *Circulation*, 113:21, p. 785.



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