About AAMI

The Association for the Advancement of Medical Instrumentation® (AAMI) is a nonprofit organization founded in 1967. It is a diverse community of 9,000 professionals united by one important mission—the development, management, and use of safe and effective health technology.

AAMI is the primary source of consensus standards, both national and international, for the medical device industry, as well as practical information, support, and guidance for healthcare technology and sterilization professionals. AAMI helps members:

- Contain costs
- Stay on top of new technology and policy developments
- Add value in healthcare organizations
- Improve professional skills
- Enhance patient care

AAMI provides a unique and critical forum for a variety of professionals including clinical and biomedical engineers and technicians, physicians, nurses, hospital administrators, educators, scientists, manufacturers, distributors, government regulators, and others with an interest in healthcare technology. AAMI fulfills its mission through:

- Courses, conferences, and continuing education, including certification programs.
- Collaborative initiatives, including summits with the FDA.
- A rich array of resources, including peer-reviewed journals, technical documents, books, videos, podcasts, and other products.

About the AAMI Foundation

Over its 50-year history, the Foundation has worked closely with its affiliate, the Association for the Advancement of Medical Instrumentation (AAMI), the world-renowned membership organization driving consensual standards in medical instrumentation.

The AAMI Foundation is committed to reducing preventable patient harm and to improving outcomes with complex healthcare technology. In addition to awarding scholarships, a research grant and its national coalition work, the Foundation works to support and promote the healthcare technology management and sterilization professionals to help drive improvements in patient safety.
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In 2011, the Association for the Advancement of Medical Instrumentation (AAMI) convened a Medical Device Alarms Summit with like-minded partners to inspire collaboration around a top challenge in healthcare: alarm system safety. At the time, alarm hazards had been a focus of sentinel alerts from The Joint Commission and national media attention. Both AAMI and ECRI Institute had identified alarm safety as a “top 10” issue. The time was right to address the hazards and the alarm burden in patient care settings.

The summit drew broad support. With AAMI taking the lead, the American College of Clinical Engineering, ECRI Institute, the Food and Drug Administration, and The Joint Commission co-convened the summit. The American Association of Critical-Care Nurses, American Society of Health-System Pharmacists, American Nursing Informatics Association, Healthcare Technology Foundation, Infusion Nurses Society, and National Patient Safety Foundation joined the co-conveners as supporting organizations.

The gathering brought together 300 people with multidisciplinary experience and expertise, including:

- Nurses, physicians, and healthcare leaders and managers
- Biomedical and information technology professionals
- Human factors engineers
- Quality and risk managers
- Academicians and researchers
- Legal experts
- Manufacturers
- Standards developers
- Regulators
- Patient safety advocates

We hope you will consider this Anthology a living reference to inform your efforts to improve alarm management practices in your healthcare organization.
The summit resulted in consensus around a shared goal: No patient should be harmed from adverse alarm system events.

The summit made clear that solving complex, technology-related safety issues would require a holistic approach. Because alarm safety issues are systems issues, making progress would be possible only with the collaboration of the entire healthcare community. The summit report, Clinical Alarms, captured clarion themes, priority issues, expert perspectives, and leading practices that pointed the way forward.

To keep the momentum going, AAMI entrusted the AAMI Foundation with leading what became a multipronged initiative. Over its 50-year history, the Foundation has worked closely with its affiliate, AAMI, the world-renowned membership organization that leads global collaboration in the development, management, and use of safe and effective healthcare technology. As AAMI’s charitable arm, the Foundation is committed to reducing preventable patient harm and improving outcomes with complex healthcare technology. The Foundation focuses on engaging the healthcare community in solving complex, multidisciplinary healthcare technology issues that require a systems approach.

A Broad Coalition to Address Complex Challenges

The AAMI Foundation recognized that addressing the whole set of complex challenges and processes identified at the summit would require an all-hands-on-deck approach. The problems cut across many domains—including diverse use environments, alarm management, systems integration, human factors, medical practice, clinician training, standards, and regulation.

In short, the scope of work required the Foundation to address the entire sociotechnical ecosystem—people, technology, organizations, and processes. For four years, this is exactly what we did.

This Anthology traces the history, breadth, and accomplishments of the Alarm Management Safety initiative, which ended in 2018. We leveraged AAMI’s deep bench of leading experts and practitioners in alarm management. We reached out to new partners. We established a broad national coalition to support and enrich our efforts. We collaborated with dozens of organizations to build awareness and knowledge about alarm management safety.

The Foundation also relied on a sound methodology to ensure rigor as we shaped research directions, developed an evidence base, showcased best practices, offered continuing education, and publicized findings. We supported major works of research and developed pragmatic, evidence-based, and actionable wise practices—and inspired safety innovations around clinical alarm management.

This Anthology aggregates the work of the Alarm Management Safety initiative in one document, which is freely and publicly available to ensure all healthcare organizations have access to this critical information. We encourage you to take advantage of the published research, collective knowledge, and practical tools and to share them with your colleagues. We hope you will consider this Anthology a living reference to inform your efforts to improve alarm management practices in your healthcare organization.

Finally, we celebrate the fact that our knowledge about how to improve alarm management safety continues to grow. The initiative kept the spotlight on a seemingly intractable set of challenges. The focus on patient safety continues in the field.
By the Numbers
AAMI Foundation Alarm Management Safety Initiative

Call to Action 2011

AAMI Foundation National Coalition for Alarm Management Safety 2014–18

Clinical Alarms Summit Report

7 Clarion Themes
31 Priorities
10 Top actions to improve alarm conditions now

25 Leading hospitals
16 Collaborating partners
15 Industry partners
11 Co-convening partners
8 Work groups

Deliverables 2014–18

41 Articles in AAMI’s peer-reviewed journal and Horizons supplement
17 Patient safety seminars
10 AAMI blog posts
9 Safety Innovations reports
3 Regional events
1 Compendium
1 Toolkit
1 Quick guide
1 Podcast
1 Library
The Call to Action
2011 Medical Device Alarms Summit

“The alarm system management is complex. Complexity bites us.”
—George Bvoke, MD, chief quality and value officer at Dartmouth-Hitchcock Medical Center

The Medical Device Alarms Summit in 2011 was an unprecedented, groundbreaking event. Framed by expert presentations, summit participants spent two days bringing questions, comments, suggestions, frustrations, and opinions about the intersection between alarm challenges and patient safety to the floor. As a community with a shared interest in patient safety, participants left the event ready to take ownership of the issues and solve the problems.

Clinical Alarms, the summit report, synthesized the discussions and laid out seven clarion themes, which served as the call to action.

Summit participants also identified actionable priority issues for each clarion theme. Taken together, the many aspects of alarm system hazards provided a comprehensive picture of the systemic challenge. Once the work of the initiative started, the list of priorities that follows was refined into a multidisciplinary action plan.

Seven Clarion Themes

1. Deepen all stakeholders’ understanding of use environments.
2. Improve alarm system management.
3. Innovate to improve alarm system integration.
4. Reconcile challenges and differences in use environments.
5. Strengthen medical electrical equipment standards and contracting language to promote success in all intended use environments.
6. Clarify regulatory requirements.
7. Share illuminating practices and lessons learning with all stakeholders.
31 Priority Issues

Deepen all stakeholders’ understanding of use environments.

1. A lack of documentation and data to analyze reported events and “near misses,” understand root problems, or support changes
2. A lack of evidence-based rationale for the configurations of alarm settings
3. Insufficient attention to human factors and usability issues
4. Technology drives healthcare processes

Improve alarm system management.

5. Determining which alarm conditions require action
6. Understanding the connections between “alarm fatigue” and patient outcomes
7. Understanding the connections between remote distributed alarm systems and “alarm fatigue”
8. Identifying “False positive alarm conditions” and clinically insignificant true positive alarm conditions
9. Delivering the right alarm condition with the right alarm signals to the right operator(s)
10. Customizing alarm limits to individual patients

Innovate to improve alarm system integration.

11. Evaluating and addressing multiple parameters simultaneously
12. Exchanging and synthesizing data from proprietary alarm systems and different medical equipment
13. Determining the source of an alarm condition—and whether an alarm condition is indicating a “false positive” alarm condition
14. Lacking clarity about who is responsible for integrating alarm conditions

Reconcile challenges and differences in use environments.

15. Strengthening core competencies in alarm system use and response
16. Reducing unnecessary alarm system malfunctions
Strengthen medical electrical equipment standards and contracting language to promote success in all intended use environments.

17. Contradictions between general and particular medical electrical equipment standards
18. Inconsistent naming of alarm conditions
19. Inability to integrate alarm condition data from different alarm systems
20. Inadequate user participation in standards development
21. Lack of user understanding of implications of “alarms off” or other alarm signal inactivation states
22. Lack of guidance on optimizing alarm limits and other default alarm settings

Clarify regulatory requirements.

23. Industry concerns about making changes to alarm systems because they might not be cleared or approved
24. Industry confusion about FDA requirements for “valid evidence” of alarm system safety and effectiveness
25. Secondary (remote notification) alarm systems used for notification

Share illuminating practices and lessons learning with all stakeholders.

26. Insufficient awareness of and attention to issues with alarm systems
27. Inadequate consideration and coordination of all facets of alarm system management
28. Limited information about front-line alarm system experiences in use environments
29. Limited information about the impact of alarm systems on patients
30. Inadequate Information about managing and using alarm systems in different healthcare settings
31. Limited opportunities to benchmark best practices
The Medical Device Alarms Summit garnered the support of six professional organizations and 14 industry sponsors. Coupled with the hundreds of deeply knowledgeable summit participants and their constituencies, this was an amazing, core group of stakeholders on which to build a movement to address the summit priorities.

### Summit Co-Conveners

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<td>American College of Clinical Engineering (ACCE)</td>
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### Summit Supporting Organizations

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### Summit Sponsors

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Immediately after the summit, the AAMI Foundation added clinical alarms to its portfolio of multidisciplinary initiatives to advance patient safety. The Foundation invited more than two dozen leading researchers, clinicians, and industry and regulatory representatives to join its Alarms Systems Steering Committee and turn the clarion themes and priority issues from the summit into an actionable agenda.

The steering committee focused its attention broadly, from conducting research reviews to building a knowledge repository, from making recommendations to regulators to developing a roadmap for hospitals to improve alarm management, and from designing alarm systems that reliably inform caregivers about patient status to differentiating alarm parameters for different patients and conditions.

The Foundation also created an Alarm Best Practices Workgroup. The efforts of the steering committee and workgroup made an impact. In 2013, for example, The Joint Commission issued a Sentinel Event Alert advising facilities to take actions to prevent alarm-related adverse patient outcomes. These recommendations aligned with the steering committee’s recommendations:

- Ensure there is a process for safe alarm management and response in high-risk areas.
- Prepare an inventory of alarm-equipped medical
devices used in high-risk areas and for high-risk conditions and identify appropriate default settings.

- Establish guidelines for alarm settings on devices used in high-risk areas and identify when alarm signals are not clinically necessary.
- Create guidelines for tailoring alarm settings for individual patients and address situations when limits can be altered to minimize alarm signals.
- Inspect, check, and maintain medical devices to provide for accurate and appropriate alarm settings, proper operation, and detectability.

The Sentinel Event Alert also recommended that all clinical care team members receive training and education on alarm management and response in high-risk areas. In addition, the alert advised healthcare facilities to look to reduce “nuisance” alarm signals and ensure that critical signals are audible in patient care areas.

Leading practitioners also prioritized major alarm management challenges for clinicians:

- The proliferation of alarmed devices in healthcare settings
- Limitations of alarm systems and devices
- Alarm burden and alarm fatigue
- Alarm management, knowledge, and education

Informed by the workgroups, the Foundation launched a Safety Innovations series of white papers, reports, and guides profiling leading healthcare organizations that are solving these types of tough safety issues related to clinical alarms. Researchers and practitioners in healthcare delivery organizations shared their best practices, challenges, lessons learned, and tips in the Safety Innovations series. Many conducted action research using data and observations from their own healthcare settings—and some conducted formal research with support from the AAMI Foundation and our partners.

In these first two years, engaged stakeholders identified tremendous research gaps in knowledge about clinical alarms, including:

- A lack of root cause analysis for alarm system issues.
- A lack of science that demonstrates the relationship between alarm parameters and patient outcomes.
- A lack of evaluation of how well clinicians recognize, understand, and learn audible alarm signals.

These important contributions led to groundbreaking studies on underexplored aspects of clinical alarms and alarm management, including alarm settings, alarm parameters, and audible alarm signals.

“We should be more patient-outcome focused. It’s also interesting how many people are affected by alarms—patients, visitors, staff, physicians, device manufacturers, healthcare technology management professionals—the list goes on and on.”

—Mark Heston, then operations director at the Cleveland Clinic, now director of clinical engineering at Children’s Hospital Colorado
As the focus of the Alarm Management Safety initiative shifted to education, communications, and promotion of evidence-based practices, the AAMI Foundation established the National Coalition for Alarm Management Safety.

The kickoff event for Phase I of the Coalition, held in April 2014, brought together close to 100 healthcare technology experts, regulators, clinical leaders, patient safety advocates, researchers, and leaders in the medical device industry to further advance the cause of improving clinical alarm safety. The coalition’s goals for 2014–16 were to:

• Enable pioneering hospitals to share their alarm management strategies, resources, and advice, and amplify their impact;
  • Advance patient safety for the nation; and
  • Help move the country toward some standardization around alarms.

This National Coalition agreed on four tangible deliverables:

1. A compendium of recommendations that synthesized the AAMI Foundation’s Safety Innovation white papers and patient safety seminars
2. A list of recommended enhancements for the medical device industry to build into future software and product versions
3. A compilation of aggregated alarm parameter data from participating hospitals

“The AAMI Foundation’s philosophy of bringing all stakeholders to the table to solve complex healthcare technology challenges yield results that are meaningful and practical, enhancing patient safety.”

—Maria Cvach, DNP, RN, FAAN, director of policy management and integration at The Johns Hopkins Health System, clinical safety specialist at the Armstrong Institute for Patient Safety and Quality, and chair of the AAMI Foundation’s National Coalition for Alarm Management Safety
4. Educational tools to teach clinicians about alarm settings and how to customize these settings for each patient

After completing Phase I of the Coalition work, participants believed there was still much work to accomplish. Therefore, Phase II of the Coalition began in July 2016. Participants agreed to expand their focus for 2016–18:

• Add ventilator alarms to the scope of work. Develop basic guidelines to help clinicians better understand the parameters and defaults for physiological monitors and ventilators—and why, when, and how to customize default parameters for particular patients.
• Create guidelines, tools, seminars, papers, and other resources to help hospitals develop alarm defaults for particular patient profiles. Develop rules/algorithms for improving alarm notification from a primary device or through middleware to reduce clinician alarm fatigue.
• Help hospitals implement American College of Cardiology and American Heart Association guidelines to prevent unnecessary telemetry monitoring.
• Address alarm sounds to be used in future iterations of the international design standard 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).

Throughout the four years and two phases of the Coalition, the Foundation employed a multimedia strategy to share illuminating practices with healthcare professionals at every level, from frontline clinicians to managers to C-suite senior leaders:

• Patient safety seminars (webinars) for targeted professional learning and continuing education, with the opportunity to earn continuing education credits
• Publications, including a Safety Innovations series and practical tools, as well as articles in AAMI’s peer-reviewed BI&T (Biomedical Instrumentation & Technology) and Horizons journals
• Outreach events for key opinion leaders in well-recognized markets
• Web directories for self-guided learning

The National Coalition helped us engage the entire healthcare community in multidisciplinary safety initiatives that would strengthen the development, management, and use of clinical alarm systems for improved patient outcomes.

“My work with the coalition helped me understand the various perspectives of different stakeholders, including nurses, physicians, academic scientists, and industry, and also pediatric vs. adult differences. We’ve shared our concerns and opportunities for improvement with our chief medical officer and vice president-level nurse leadership. We have a safety initiative now to reengineer the ways we monitor patients in the hospital and at home. Our team reviewed the coalition materials as part of our internal planning process. The AAMI Foundation’s Mary K. Logan research grants have also enabled innovation in this space.”

—Chris Bonafide, research director for pediatric hospital medicine at Children’s Hospital of Philadelphia
Eight National Coalition Work Groups and Select Accomplishments

National Coalition participants rolled up their sleeves to address priority issues during their four-year engagement with the AAMI Foundation. Highlights of their accomplishments:

1. SpO2 alarm management. This group led the development of the **SpO2 Alarm Management Toolkit**, which is designed to help healthcare organizations optimize patient safety by providing resources, strategies, and approaches to mitigate nonactionable (clinically insignificant) SpO2 (saturation of peripheral oxygenation) alarm signals.

2. Alarm taxonomy. This group collaborated with AAMI’s Medical Device Alarms Standards Committee to develop standardization around alarm terms used by industry.

3. Competencies, training materials, and tests for alarm management. This group created a toolkit for nurse leaders, published in *Clinical Nurse Specialist*, to establish a baseline set of wiser practices in the safe and effective use of physiological monitors related to alarm management.
4. Building a national research database, and a database of hospital default settings. This group created an Alarm Parameter Inventory for healthcare organizations to record default settings on alarm parameters on common hospital units, which they can use to comply with The Joint Commission’s 2014 National Patient Safety Goal.

5. Collection, analysis, and monitoring of alarm data. This group conducted complex analysis of alarm data, which informed the development of two technical information reports by the AAMI’s Medical Device Alarms Standards Committee: AAMI TIR66:2017, Guidance for the creation of physiologic waveform databases to demonstrate reasonable assurance of the safety and effectiveness of alarm system algorithms, and AAMI TIR71:2017, Guidance for logging of clinical and forensic alarm data.

6. Helping hospitals become high-reliability organizations. This group developed a framework for alarm management process maturity to help make patient environments safer with a more rational, evidence-based approach. Alarm management is a component of a much larger initiative for hospitals to become high-reliability organizations.

7. Monitor watchers. This group conducted a national online survey, primarily of nurses, to examine monitor watcher practices. Research: Use of Monitor Watchers in Hospitals: Characteristics, Training, and Practices details their findings.

8. Ventilator alarms. This group benchmarked best practices in ventilator alarm management and clinician education for ventilator alarms. This group’s work also reflected priority issues from the 2014 AAMI/FDA Summit on Ventilator Technology. Many work group participants also shared their findings and strategies in AAMI Foundation patient safety seminars and in presentations to professional associations.

How the AAMI Foundation Selects and Builds National Coalitions

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<tr>
<td>• Conduct comprehensive review of current and emerging issues</td>
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<td>• Engage stakeholder communities</td>
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<td>• Vetting process with AAMI Foundation partners</td>
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<th>Convene Critical Stakeholders</th>
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<td>• Engage stakeholder organizations</td>
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<td>• Host think tank meeting</td>
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<td>• Ensure collaborating partners are involved</td>
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<th>Communicate and Enlist Support</th>
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<td>• Engage stakeholder organizations in publicizing and disseminating deliverables</td>
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Research Highlights
The National Coalition recognized the growing alarm burden in clinical care settings, from the types of alarm signals to the challenge of making sense of alarm sounds. Coalition members conducted several research studies to overcome the challenges in clinical practice and in industry. For example:

Maria Cvach, director of policy management and integration at The Johns Hopkins Health System, clinical safety specialist at the Armstrong Institute for Patient Safety and Quality, and chair of the AAMI Foundation’s National Coalition for Alarm Management Safety, has taken an evidence-based approach to alarm management.

At The Johns Hopkins Hospital, Cvach led efforts to use data to drive alarm system improvement efforts, from gathering and analyzing quantitative data to identifying the contributing conditions to alarm burden and alarm fatigue. At the kickoff meeting of the coalition, she identified the top five knowledge gaps related to alarm management to set an agenda for researchers and practitioners:

1. Lack of documentation and data to analyze reported events and near misses to understand root problems
2. Lack of evidence-based rationale for the configurations of alarm settings
3. Lack of understanding of the best types of alarm signals to elicit a response
4. Lack of knowledge regarding who should be monitored and for how long
5. Lack of understanding about the best secondary alarm notification systems

Among many other contributions to the National Coalition, Cvach also worked closely with the AAMI Foundation to create the critically important Clinical Alarm Management Compendium, which provides the alarm management settings used by many forward-thinking hospitals.

Timeline

- **Medical Device Alarms Summit**
  - October 2011

- **Clinical Alarms Summit report**
  - December 2011

- **Research and evidence-based data collection**
  - 2012–15

- **Safety Innovations Series**
  - 2012–16

- **Published Research, Articles, and Outreach Events**
  - 2011–20

- **Patient Safety Seminars**
  - 2014–18

- **Promoting solutions and best practices**
  - 2014–18

- **National Coalition for Alarm Management Safety launches**
  - April 2014

- **Clinical Alarm Management Compendium**
  - April 2015
Judy Edworthy, director of the Cognition Institute and professor of applied psychology at the University of Plymouth, UK, created and validated new auditory alarm signals using modern psychoacoustic principles for medical equipment. The new alarm sounds were designed and tested for:

- Learnability (how easy they are to learn and remember).
- Localizability (listeners’ ability to detect where the sound is coming from in 3D space).
- Performance in a more realistic, simulated environment and in other more realistic settings that use typical noise and/or involve a clinician or other participant doing other tasks at the same time.

Key medical device standards committees fast-tracked an amendment to international standards for medical electrical equipment to reflect this research. The International Technical Commission (IEC) and International Standards Organization worked jointly on Amendment 2 to IEC 60601-1-8, *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*. The amendment was approved internationally in 2020. AAMI plans to adopt this standard in 2021.

Daniel McFarlane, principal scientist at Philips Healthcare, was an alarm safety subject matter expert for military combat systems before being recruited by AAMI President and CEO Emeritus Mary Logan to refocus his career on alarm safety for healthcare. He secured U.S Department of Defense funding to conduct a foundational study on alarm safety for healthcare, and published the results in the *PLoS One* journal. “My organization is a world-leading manufacturer of medical devices, and it is discussing how to improve alarm safety design,” he said.
Putting Knowledge into Practice

“This information is extremely valuable to clinicians. It is a wonderful resource for harried managers who can find all the necessary resources in one place.”

—Cheryl Hoerr, director of respiratory services, Phelps Health in Rolla, MO

The work of the National Coalition for Alarm Management Safety has helped Cheryl Hoerr, director of respiratory services at Phelps Health in Rolla, MO, develop “a greater appreciation of the processes outside of the critical care environment that affect clinical alarm systems.

“As a clinician,” Hoerr added, “I am essentially the ‘end user.’ I now understand that clinical alarms must be evaluated in the planning, evaluation, and purchase phases before ever being introduced to the patient care environment.” As chair of her hospital’s clinical alarms committee, she has shared this knowledge with team members, who are implementing new processes to ensure clinical alarms are considered when evaluating new equipment.

The team also has implemented a new process for intake of new equipment. Clinical Engineering assesses alarm system functioning and sets alarm signal volumes before any staff training begins. The team used resources from the National Coalition, including case studies and webinars, to develop a training program for all staff on the importance of critical alarms to patient safety, which is now a mandatory annual training.

The National Coalition’s work led the healthcare system to make alarm management safety a priority—and the coalition’s resources convinced a key stakeholder that action was necessary. This resulted in surveys, pilot projects, and improvements to alarm systems management.

“This was a significant safety initiative that benefited many healthcare institutions.”

—Mike Capuano, manager of biomedical technology at Hamilton Health Sciences in Hamilton, Ontario

“We used the toolkits as we developed a very detailed, step-by-step policy.”

—Corrina Johnson, nurse manager at Regional Health in Rapid City, SD

Gaining an understanding of the implications of alarm fatigue from the National Coalition led to a large, multidisciplinary team to address the issues at Monument Health (formerly Regional Health) in Rapid City, SD.
A Robust Collection of Knowledge
2014–18

The Call to Action
Deliverables from the
Medical Device Alarm Summit
2011

Summit Report
Clinical Alarms
AAMI (2011)
This report issues a call to action to address the challenges around alarm management. It includes:
• Seven clarion themes and 31 priority actions
• Top 10 actions you can take now
• Summaries of presentations, expert perspectives, and leading practices.

Beyond the Summit
AAMI Foundation
Safety Innovations Series
2012–16

Plan, Do, Check, Act: Using Action Research to Manage Alarm Systems, Signals, and Responses: The Beth Israel Deaconess Medical Center
Vockley, M. (2012)
Beth Israel Deaconess Medical Center responded to two alarm-related sentinel events by quickly identifying opportunities for short-term fixes to a multifaceted problem and then longer-term solutions and innovations.

Recommendations for Alarm Signal Standardization and More Innovation: The Christiana Care Health System Experience
Vockley, M. (2012)
Christiana Care Health System 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.

Using Data to Drive Alarm System Improvements: The Johns Hopkins Hospital Experience
Williams, J. (2012)
For Johns Hopkins Hospital, the key to reducing alarm signal noise is the collection and analysis of quantitative data to evaluate the applications of alarm system management in hospitals.
**Cardiopulmonary Monitors and Clinically Significant Events in Critically Ill Children: Children’s National Medical Center**


A team of nurses, biomedical engineers, physicians, and biostatisticians were assembled to assess the conditions associated with the generation of cardiopulmonary monitors, including false positive alarm signals in critically ill children, and to define alternative alarm parameters that would improve alarm performance.

**Safeguarding Patients with Surveillance Monitoring: The Dartmouth-Hitchcock Medical Center Experience**

Vockley, M. (2013)

A series of adverse events led clinicians and researchers at Dartmouth-Hitchcock Medical Center to a humbling conclusion: Healthcare professionals were handicapped by their limited ability to detect signs of patient deterioration and to predict which patients were at risk for adverse events in the first place. Dartmouth-Hitchcock responded with stopgap measures to safeguard patients, including double checks of opioid administration, smart patient-controlled analgesia pumps, and rapid response teams. The Dartmouth-Hitchcock team also developed alarm thresholds, notification delay time, and a system for alarm parameter adjustments.

**Simple Solutions for Improving Patient Safety in Cardiac Monitoring—Eight Critical Elements to Monitor Alarm Competency**


The University of Pittsburgh Medical Center (UPMC) is a large, multi-hospital system. Through pilot programs and trial and error, the healthcare system and UPMC Presbyterian Hospital sought to find commonalities in alarm management between different units.

**Clinical Practice Changes Associated with Alarm Standardization: The Boston Medical Center Experience**

Lipschultz, A. (2014)

Boston Medical Center responded to national attention on alarm fatigue and reports of sentinel events from missed alarm signals by reconvening a multidisciplinary task force to look for opportunities to decrease the volume of audible alarms, particularly on its medical surgical units.
Healthcare Alarm Safety—What We Can Learn from Military Alarm Management Strategies  
Allen, J.S. (2014)  
Daniel McFarlane of Lockheed Martin Advanced Technologies Laboratories provides insight on ways to enhance hospital alarm management, reflecting upon innovative alerting systems utilized by the Navy to improve warfighter awareness and capabilities.

Fighting Alarm Fatigue with Data-Driven Interventions: The NCH Healthcare Device Eco-System Experience  
Epstein, M.L., Smith, K., & Snavely, V. (2016)  
NCH Healthcare System turned its attention to alarm management in response to The Joint Commission’s National Patient Safety Goals, using data to inform decisions on nonactionable tachycardia alarms.

Practical Strategies for Executives, Risk Managers, and Clinical Leaders  
Deliverables from the AAMI Foundation’s National Coalition for Alarm Management Safety  
2015–18

“...AAMI pulled together a cross-disciplinary team to develop an alarm compendium for hospitals and health systems as a best practices guide to help navigate the complexities of alarm management. The compendium gives real-world examples used by other hospitals that can be implemented to reduce alarms such as alarm reports, education and competencies, and applications of tools such as failure modes effect analysis. The compendium also provides default parameter settings for multiple facilities of varying sizes and complexities.”  
—Samantha Jacques, PhD, FACHE, director of clinical engineering for the Penn State Health System, in TechNation

Alarm Management Quick Guide  
Managing Smart Pump Alarms: Reducing Alarm Fatigue  
AAMI Foundation (2018)  
This guide provides a starting point for healthcare institutions to begin to explore their large-volume and syringe pump alarms and understand potential strategies to mitigate nonactionable alarms.

Practical Tools  
10 Steps Toward Safer Alarm Management

Alarm Parameter Inventory

Alarm System Vocabulary

Special Publication  
Clinical Alarm Management Compendium (2015)

Toolkit  
SpO2 Alarm Management Toolkit  
Piepenbrink, J., & Sendelbach, S., (Eds.) (2018)
Spreading the Word

Social media is key to informing all those who are concerned about patient safety that there are tools developed by national experts to assist in reducing harm with infusion therapy. Over the four years of this effort, AAMI and AAMI Foundation have made use of Facebook and Twitter to get the word out about the recommendations and solutions available to the clinical community.

Education and Knowledge Sharing

AAMI Foundation Annual Regional Events 2015–17

The AAMI Foundation provided live, interactive learning experiences during three annual regional events, where sessions highlighted the work of the Foundation’s National Coalition on Alarm Management, National Coalition for Infusion Therapy, and National Coalition to Promote Continuous Monitoring of Patients on Opioids.

“Since the AAMI Foundation launched its first national coalitions, we’ve found that providing clinicians and their healthcare technology industry partners with the opportunity to meet face to face encourages knowledge sharing and communication in a way that online seminars can’t.”

—Marilyn Neder Flack, executive director emeritus of the AAMI Foundation

Alarm Management Presentations  Boston • Oct. 14, 2015 • 85 participants

Audible to Actionable: Alarm Management at Beth Israel Deaconess Medical Center

Tricia Bourie, RN, MS, program director of nursing informatics at Beth Israel Deaconess Medical Center

Alarm Management at Boston Medical Center: A Roadmap to Safe Silence

Jim Piepenbrink, director of clinical engineering at Boston Medical Center
**Alarm Management Presentations**  
Chicago • Sept. 27–28, 2016 • 113 participants

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<tr>
<th>Title</th>
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| It’s Not Just About the Alarms: Reducing Failure to Rescue             | Christina Taylor, RN, MSN, CCRN, nurse manager at Wake Forest Baptist Hospital  
Kristina Foard, RN, MSNEd, SCRN, nurse practice specialist at Wake Forest Baptist Health |
| No Cause for Alarm: A Holistic Approach to Identification, Prioritization, and Reduction | Pascha E. Schafer, MD, FACC, medical director of the cardiac care unit and the Medical College of Georgia at Georgia Regents University |
| Interruption Fatigue: What Is the Overall Impact?                     | Kim Velez, BSN, RN, clinical informatics specialist at Saint Joseph Hospital in Denver                                                      |
| Are You Connected: Get Ready to Reduce Alarms, Avoid Alarm Fatigue, and Improve Patient Safety | Cathy Sullivan, associate director of sourcing at Mount Sinai Beth Israel Hospital |
| A Case Study on Ventilator Alarm Management                           | Connie Dills, MBA, RRT, RPFT, respiratory practice manager at the Hospital for Special Care in New Britain, CT |
| Alarm Management Through Rule-Based Middleware and Smart Phones       | Inhel Rekik, MS, clinical engineer at the University of Maryland Medical Center  
George Reed, MBA, enterprise director of clinical engineering at Jefferson University Hospitals in Philadelphia |
| Driving the Culture of Alarm Management Practices: Using the Influencer Model | Karen Peters, MSN, RN, CMSRN, RN-BC, AGCNS-BC, clinical practice specialist at Winchester Hospital, MA  
Sheila Shields, MSN, RN, CCRN, RN-BC, clinical practice specialist at Winchester Hospital, MA |
| Sustaining a Successful Alarm Management Program                      | Kevin Smith, BSN, RN, CNML, CVRN-BC, director of cardiac services at NCH Healthcare System |
| The Role of Middleware in Alarm Management                            | Sue Carol Verillo, RN, MSN, CRRN, nurse manager at The Johns Hopkins Hospital, on behalf of Sharon Allan, ACNS-BC, Run MSN, CCRC, and Maria Cvach, DNP, RN, FAAN, director of policy management and integration at The Johns Hopkins Health System, clinical safety specialist at the Armstrong Institute for Patient Safety and Quality, and chair of the AAMI Foundation’s National Coalition for Alarm Management Safety |
Alarm Management Presentations
San Diego • Nov. 18–19, 2017 • 95 participants

A Journey to Reduce Alarm Fatigue: Tips on What Not to Do
Peggy Bartholomew, MHSM, RN, PMP, project manager of quality project management at UT Southwestern Medical Center

Avera Heart Hospital’s Journey to Alarm Management Improvement
Cheryl Osmond, RN, MS, vice president of clinical services at Avera Heart Hospital

UCSF Alarms
Kevin Spolini, MSN, RN, manager of clinical informatics at UCSF Benioff Children’s Hospital

Precise Patient Monitoring with Few False Alarms: SuperAlarm
Xiao Hu, PhD, associate professor of physiological nursing and neurological surgery at the Institute of Computational Health Sciences at the University of California, San Francisco

Update on National Patient Safety Goal 6: Reduce the Harm Associated with Clinical Alarm Systems
Gerry Castro, PhD, MD, project director of patient safety initiatives at The Joint Commission

Patient Safety Seminars
2014–18

Beginning in 2014, AAMI Foundation hosted a series of patient safety seminars (webinars) that showcased research, best practices, and case studies of initiatives in healthcare organizations to improve alarm management safety. The Foundation offered Certificates of Participation as a continuing education credit for each seminar.

Use of Middleware in Alarm Management: Ancillary Notification and Obtaining Alarm Data • January 2014
Paul Coss, RN, principal at Coss Associates
Ramya Krishnan, MS, senior project engineer at ECRI Institute’s Health Devices Group
Tim Gee, BA, principal at Medical Connectivity Consulting
Andrew Currie, MS, director of clinical engineering at The Johns Hopkins Hospital
Marjorie Funk, PhD, RN, RAHA, FAAN, professor at Yale University School of Nursing

Current Challenges with Ventilator Alarms • March 2014
Thomas Krüger, senior product manager for respiratory care at Dräger Medical GmbH
Russelle A. Cazares, MHA, RRT, PCS manager of respiratory care services at Children’s Hospital Los Angeles
Matthew P. Trojanowski, MSc, RRT, manager of adult respiratory care services, anesthesiology, and critical care medicine at The Johns Hopkins Hospital
Shawna Strickland, PhD, RRT-NPS, AE-C, FAARC, associate executive director of education at the American Association for Respiratory Care
Educating and Training Your Staff: Circling Back to Your Policies and Procedures • April 2014

James Piepenbrink, BSBME, director of clinical engineering at Boston Medical Center

Jaspreet Mankoo, BS, clinical engineering intern at VA Boston Healthcare System, UConn Clinical Engineering MS Program

Ekta Srinivasa, RN, clinical resource nurse at VA Boston Healthcare System

Russell S. Coggins, RN, MSN, clinical nurse advisor for critical care in the office of nursing services (field-based), and nurse manager of the surgical ICU at Charles George VAMC

Maria Cvach, DNP, RN, CCRN, director of policy management and integration at The Johns Hopkins Health System, clinical safety specialist at the Armstrong Institute for Patient Safety and Quality, and chair of the AAMI Foundation’s National Coalition for Alarm Management Safety

Marjorie Funk, PhD, RN, FAHA, FAAN, professor at Yale University School of Nursing


Shawna Strickland, PhD, RT-NPS, RRT-ACS, associate executive director of the American Association for Respiratory Care

Jenifer Burke, RN, MSN, CPNP, Rush University Medical Center

Sounding the Alarm! How Accurate Are Your Counts? • June 2015

Mary Baum, president and CEO of Baum, Arenmeier and Talent

Alarm Management: From Confusion, to Information, to Wisdom • August 2015

Kevin Smith, BSN, RN, CNML, CVRN-BC, director of cardiac telemetry at Naples Community Healthcare System

Samantha Jacques, PhD, FACHE, director of biomedical engineering at Texas Children’s Hospital

Effects of Patient Load and Other Monitoring System Design Choices on Inpatient Monitoring Quality • August 2015

Melanie Wright, PhD, program director of patient safety research at Trinity Health and Saint Alphonsus Health System

Noa Segall, PhD, assistant professor at Duke University Medical Center

Enhancing Patient Safety with Appropriate Ventilator Alarm Management • September 2015

Dario Rodriguez, Jr., MSc, RRT, RPFT, FAARC, director of clinical research at the University of Cincinnati
Alarm Safety Updates: Are You Ready? • October 2015

Ronald M. Wyatt, MD, MHA, IHI Merck Fellow 2010, medical director in the Office of the Chief Medical Officer, The Joint Commission

Maria Cvach, DNP, RN, FAAN, director of policy management and integration at The Johns Hopkins Health System, clinical safety specialist at the Armstrong Institute for Patient Safety and Quality, and chair of the AAMI Foundation’s National Coalition for Alarm Management Safety

Sharon H. Allan, ACNS-BC, MSN, RN, CCRC, CVSICU clinical nurse specialist at The Johns Hopkins Hospital

Creating a Culture of Safety in Home Mechanical Ventilation • December 2015

Angela King, BS, RPFT, RRT-NPS, CEO, owner, and vice president of clinical services, Mobile Medical Homecare

Ronda Bradley, MS, RRT, FAARC, owner of Spiritus Consultants

ePod (Early Predictor of Deterioration) • January 2016

Kathy J. Simpson, BSN, RN, director of the medical emergency team, Intermountain Medical Center

Kathryn G. Kuttler, PhD, director of clinical, quality and research medical informatics, Homer Warner Center, Intermountain Healthcare

R. Scott Evans, MS, PhD, medical informatics director, Intermountain Healthcare, and professor of biomedical informatics, University of Utah

Cathy Sullivan, MSN, RN, FNP, CCRN, associate director of sourcing at Mount Sinai Beth Israel Hospital

The Journey of Intelligent Alarm Management in a NICU • December 2016

Greg Walkup, director of IT, Sentara

Monique M. Lowery, BSN, RNC-NIC, Sentara

Helping Hospitals Struggling to Obtain Baseline Alarm Data and to Reduce Non-Actionable Alarms • April 2017

Stephanie D. Orr, DNP, RN, CCRN, NeuroScience Intensive Care Unit, Rush University Medical Center

A Journey to Reducing Alarm Fatigue: Tips on What Not to Do • September 2017

Peggy Bartholomew, MHSM, RN, PMP, project manager of quality project management, UT Southwestern Medical Center

Utilizing Lean Methodologies to Manage Telemetry Devices • October 2017

Christina Carranza, MSN, RN-BC, CNML, Naples Community Hospital

UCSF’s Experience Sending Alarms to Phones in the Intensive Care Nursery • December 2017

Kevin Spolini, MSN, RN, UCSF Benioff Children’s Hospital

Clinical Alarm Management Strategies—Meaningful Alerts: Reducing Non-actionable Alarms • January 2018

Sharon H. Allan, DNP, RN, ACNS-BC, The Johns Hopkins Hospital
Going Deeper
Articles and Case Studies from AAMI and the AAMI Foundation
2011–19

*BI&T (Biomedical Instrumentation & Technology)*, AAMI’s peer-reviewed journal

**The Use of Mobile Devices to Improve Alarm Systems**
Hoglund, D., & Elms, J. (September/October 2011)

**Wireless Systems and Alarm Management**
Moon, J.

**Monitor Alarm Fatigue: An Integrative Review**
Cvach, M. (July/August 2012)

**The Complexity of Clinical Alarm Systems**
Lipschultz, A. (May/June 2014)

**Research: Video Methods for Evaluating Physiologic Monitor Alarms and Alarm Responses**

**Safety Innovations: Healthcare Alarm Safety—What We Can Learn from Military Alarm Management Strategies**
Allen, J.S. (May/June 2014)

**Decreasing False Alarms by Obtaining the Best Signal and Minimizing Artifact from Physiological Sensors**
Block, F.E. III, and Block, F.E. Jr. (November/December 2015)

**Research: Effect of Altering Alarm Settings: A Randomized Control Study**

**Case Study: Reducing Interruption Fatigue through Improved Alarm Support**
Jahrsdoefer, M. (March/April 2016)

**Framework for Alarm Management Process Maturity**

**Roundtable Discussion: Improving the ‘Alarm Problem’ Will Require Much More Than Just Reducing the Number of Alarms**
(November/December 2018)
Research, Guidance, and Strategies
Expanding on Recommendations in the
Clinical Alarm Management Compendium

Research: Use of Monitor Watchers in Hospitals: Characteristics, Training, and Practices

Research: Acceptability, Feasibility, and Cost of Using Video to Evaluate Alarm Fatigue

Improving Clinical Alarm Management: Guidance and Strategies

Customizing Alarm Limits Based on Specific Needs of Patients
Cvach, M., Kitchens, M., Smith, J., Harris, P., & Flack, M.N. (May/June 2017)

Two AAMI Horizons Issues Dedicated to Alarm Management
In the lead-up to the summit on clinical alarms in the fall of 2011, the Spring 2011 issue of Horizons, the AAMI BI&T biannual supplement, was dedicated to alarm management. Six years later, AAMI revisited this thematic topic in the Spring 2017 issue.

These two issues are rich repositories of alarm management knowledge, including big-picture perspectives, approaches to clinical alarm management in practice, alarm system research and design, standards development, and commentaries.

Improving Medical Alarm Systems
Spring 2011 Horizons

The Big Picture
A Roundtable Discussion: Alarm Safety: A Collaborative Effort

Spotlight on Medical Alarms in Home Healthcare

An FDA Response on Alarm System Issues

Clinical Practice
Keller, J.P., Diefes, R., Graham, K., Meyers, M., & Pelczarski, K.
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<td>Alarms Research</td>
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<td>Physiological Monitoring Alarm Load on Medical/Surgical Floors of a Community Hospital</td>
<td>Gross, B., Dahl, D., &amp; Nielson, L.</td>
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<td>An Evidence-Based Approach to Reduce Nuisance Alarms and Alarm Fatigue</td>
<td>Welch, J.</td>
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<td>Highlights of the New International Standard: Alarm Systems and Ventilators in Critical Care</td>
<td>Milamed, D.R., &amp; Dorsch, S.E.</td>
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<td>Point-Counterpoint: IEC 62D Medical Monitor Standards Will Makes Alarms Worse</td>
<td>Block, F.E. Jr.</td>
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<td>Experts Debate International Alarm Standards: Changes to the Alarm Standard Are Crucial to Ensure Patient Safety</td>
<td>Woehrle, D.</td>
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<td>Alarm System Design</td>
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<td>Complementing Medical Device Alarms with Animated Guidance</td>
<td>Wiklund, M., &amp; Kendler, J.</td>
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<td>Beyond Sound: Using Systems Integration to Advance Alarm Functionality</td>
<td>Dyell, D.</td>
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<td>Functional Basics of Third-Party Alarm Notification Systems</td>
<td>Moorman, B.A., &amp; Gee, T.</td>
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<td>Commentary</td>
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<tr>
<td>Toward Better Medical Alarm Systems</td>
<td>Hedley-Whyte, J.</td>
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This issue includes substantial contributions from the AAMI Foundation’s National Coalition for Alarm Management Safety.

**The Big Picture**

*AAMI Tackles Alarm Management Standards*
Moyer, J.

*A Roundtable Discussion: Navigating the Noise with Clinical Alarm Management*

**Approaches to Clinical Alarm Management**

*Factors that Affect Design of Secondary Alarm Notification*
Jacques, S.

*Developing a Clinical Alarms Management Committee at an Academic Medical Center*

*Alarm Management Lessons from the Process Industries*
Forrest, S., & Sands, N.

*Improving Patient Safety through the Use of Nursing Surveillance*
Giuliano, K.K.

*Using Middleware to Manage Smart Alarms for Patients Receiving Opioids*
Zaleski, J., & Venella, J.

*Classifying Alarms: Seeking Durability, Credibility, Consistency, and Simplicity*
Edworthy, J.R., Schlesinger, J.J., McNeer, R.R., Kristensen, M.S., & Bennett C.L.

**Case Study**

*Reduction of Nonactionable Alarms in Medical Intensive Care*
De Vaux, L., Cooper, D., Knudson, K., Gasperini, M., Rodgerson, K., & Funk, M.

*Managing Mechanical Ventilator Alarms with Middleware*
Dills, C.C.

*Using the Influencer Model to Improve Alarm Management Practices*
Peters, K., & Shields, S.

**Commentary**

*Drawing Up a New Game Plan to Reduce Alarm Fatigue*
Venella, J.
AAMI Blog Posts

Tim Vanderveen: Medical Device Alarms and Hospital Noise (Aug. 10, 2012)

Tim Vanderveen: Don’t Approach the Challenges of Pump Alarms with a Broad Brush (May 28, 2014)

William Hyman: Learning from Nonactionable Clinical Alarms (Oct. 6, 2014)

AAMI Podcast

Episode 17: Clinical Alarm Management (Feb. 19, 2016)

Media Coverage

How Redesigning the Abrasive Alarms of Hospital Soundscapes Can Save Lives

“Alarm Management Revisited – Quieting the Noise Through Knowledge”
Conclusion

When warnings about clinical alarm safety hazards rocked the healthcare community a decade ago, AAMI and the AAMI Foundation heeded the call.

We recognized that addressing alarm management and alarm burden challenges would require moving beyond siloed approaches. We played a leadership role in convening a multidisciplinary summit, reaching consensus on the most pressing priorities, forming volunteer committees of experts, and launching the National Coalition for Alarm Management Safety.

A high level of interest and sustained engagement by hundreds of volunteers and more than three dozen professional organizations and corporate partners led to an ambitious scope of work to promote the safe and effective use of alarm systems. The volunteers were so dedicated to solving alarm management challenges that they extended their initial two-year commitment to a second two-year phase, which led more experts to join the Coalition.

The lasting result is a robust collection of knowledge about clinical alarm safety that can inform research, practice, and innovation to benefit the most important healthcare stakeholder: patients. Even as clinical technology and alarm systems continue to change, this body of work—which covers the entire sociotechnical ecosystem of people, technology, organizations, and processes—remains relevant, accessible, and useful to the field.

From a toolkit to a quick guide to a compendium, from professional development in patient safety seminars to robust research and case studies, there is something for everyone, including:

- Healthcare executives, medical professionals, and quality and risk managers.
- Biomedical and information technology professionals.
- Researchers and educators.
- Device manufacturers, systems integrators, and innovators.
- Standards developers and regulators.

AAMI and the AAMI Foundation thank everyone who participated in promoting the safe and effective use of clinical alarm systems. We invite you to share this Anthology with your colleagues and peers.
Co-Convening Organizations
- American Association of Critical-Care Nurses (AACN)
- American College of Clinical Engineering (ACCE)
- American Society for Healthcare Risk Management (ASHRM)
- ECRI Institute
- Healthcare Technology Foundation (HTF)
- Hospital Quality Institute (HQI)
- National Patient Safety Foundation (NPSF)
- Premier Safety Institute
- Regenstrief Center for Healthcare Engineering
- The Joint Commission
- VA National Center for Patient Safety

Corporate Partners

Diamond Level
- BD
- CU Medical
- Connexall
- Masimo
- Medtronic

Gold Level
- Cerner
- Bernoulli
- Draeger
- Mindray
- Nihon Kohden

Platinum Level
- GE Healthcare
- Philips

Collaborating Partners
- American Association for Respiratory Care (AARC)
- American College of Clinical Engineering (ACCE)
- American Hospital Association (AHA)
- American Organization of Nurse Executives (AONE)
- American Society for Health Care Risk Management (ASHRM)
- Association of periOperative Registered Nurses (AORN)
- ECRI Institute
- Healthcare Technology Foundation (HTF)
- Hospital Quality Institute (HQI)
- Infusion Nurses Society (INS)
- Institute for Safe Medication Practices (ISMP)
- National Association of Clinical Nurse Specialists (NACNS)
- National Patient Safety Foundation (NPSF)
- Premier
- Regenstrief National Center for Medical Device Informatics (REMEDi Central)
- The Joint Commission
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Nancy Sorensen  
Vocera Communications

Ray Snider  
Emory University Hospital

Greg Spratt  
Medtronic

Bob Steurer  
Spacelabs Healthcare

Lloyd Stern  
Draeger

Janet Stifter  
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Shawna Strickland  
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GE Healthcare

Neal Thurman  
Cerner Corporation

Jacob Turmell  
Philips Healthcare

Sue Carol Verrillo  
The Johns Hopkins Hospital

Sharon K. Wahl  
Abbott Northwestern Hospital

Greg Walkup  
Sentara Healthcare

Brian K. Walsh  
American Association for Respiratory Care

James P. Welch  
Sotera Wireless Inc.

Sheila Whalen  
Rush University Medical Center

Anita White  
Cleveland Clinic

Sarah Williams  
Bernoulli

Lori Lynn Wood  
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