AAMI
Advancing Safety in Healthcare Technology

Creating a Culture of Safety

Priority Issues from the 2014 AAMI/FDA Summit on Ventilator Technology

Summit Conveners

AAMI

The Association for the Advancement of Medical Instrumentation (AAMI), a nonprofit organization founded in 1967, is a diverse alliance of nearly 7,000 members from around the world united by one critical mission—supporting the development, management, and use of safe and effective healthcare technology. AAMI serves as a convener of diverse groups of committed professionals with one common goal—improving patient outcomes. AAMI also produces high-quality and objective information on healthcare technology and related processes and issues. AAMI is not an advocacy organization and prides itself on the objectivity of its work.

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About this Report

This publication covers the clarion themes, challenges, and priority actions developed by consensus at the summit. The report summarizes summit presentations and provides additional perspectives from experts. This publication is intended to be a helpful information resource, and it reflects the expert advice and views of the summit experts. It is not to be construed as an interpretation of AAMI standards, and it does not constitute legal or regulatory advice.

More Summit Information on AAMI Website

The summit agenda, presentations, updates, and reference materials—including "Clearing the Air: Innovations and Complications with Ventilator Technology" from the July/August 2014 issue of *Biomedical Instrumentation & Technology*—are posted on www.aami.org/summit2014.

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PRIORITY ISSUES FROM THE 2014 AAMI/FDA SUMMIT ON VENTILATOR TECHNOLOGY

Contents

Keeping Patients Front and Center

Dear Colleagues,

On Sept. 16 and 17, 2014, more than 160 talented and passionate multidisciplinary stakeholders brought their incredible expertise, personal experiences, and wisdom into a room to plunge into the clinical, technical, and regulatory challenges with a single piece of technology they know well: ventilation technology. They were well prepared for the plunge and, at the end of the event, came away with a clear and compelling action plan.

The presentations, discussions, and thus this report focused on problems with ventilation technology. Heard throughout the event, though, was a continuous drumbeat about the miracle of life made possible by ventilation technology. Stephen Mikita, an assistant attorney general for the state of Utah, who suffers from spinal muscular atrophy, gave his compelling first-hand story of the life-saving and sometimes terrifying experience of relying on ventilators. Today's ventilators have advanced over and beyond the first subatmospheric ventilation devices used in the 1920s and 1930s.

Even so, it was clear throughout the summit that we still have a long way to go before declaring victory on the mastery of the technology and clinician understanding of how to use it properly. The action plan developed collectively by summit attendees clearly outlines where we all need to go—together.

One of the favorite aspects of the summit model—for AAMI, the FDA, and the attendees—is the collaboration that develops among individuals who don't always agree and in fact may strongly disagree on some of the issues. In the end, everyone to a person keeps patients such as Stephen Mikita front and center.

Thank you to all who participated and provided expertise and leadership to make this event such a success. And, to you, the reader, thank you for continuing to turn the pages of this publication to learn what's next and how you can help.

Sincerely,

Mary Logan
President
Association for the
Advancement of
Medical Instrumentation

Scott A. Colburn
Commander, U.S. Public Health Service
Director, Standards Program
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Executive Summary

"We have to pull in all of the ideas and use the knowledge gained from previous summits, because so many topics apply horizontally to many medical devices."

—Scott Colburn
Commander, U.S. Public Health Service
Director, FDA CDRH Standards Program

Living in an era of technological innovation in healthcare is something of a grey area—somewhere between safety and risk, clarity and confusion, confidence and concern.

The 2014 AAMI/FDA Summit on Ventilator Technology shed light on this murkiness. "Ventilators are critical life-support devices that provide respiratory therapy to thousands of patients every day," said summit presenter Hilda Scharen, a senior science health advisor at the FDA Center for Devices and Radiological Health (CDRH). No patient who labors for each breath wants to go back to the days before there were mechanical ventilators. No clinician caring for patients with breathing conditions wants to be without this advanced medical technology, which offers "life-saving support for a wide variety of patients and patient care settings," in the words of summit presenter Anya Harry, branch chief of the FDA CDRH Respiratory Devices Branch.

Yet, "with all the advances in technology, we also see clinical challenges that go hand in hand with the advances and risks that need to be addressed," she said. "We have an opportunity to address the challenges with a multidisciplinary approach."

These assertions echoed similar observations at all five previous AAMI/FDA summits, which illuminated wide-ranging challenges with infusion devices, clinical alarms, medical device reprocessing, medical device interoperability, and healthcare technology in nonclinical settings. Advanced medical technology helps millions of people live better lives and gives clinicians powerful tools for patient care. But complexity and inconsistency can compromise patient safety and lead to unintended consequences. Technology challenges are intrinsically connected to leadership, clinical, regulatory, market, and human challenges. "Device" challenges are actually *systems* challenges.

Participants at this year's summit, most of whom had not attended previous summits, repeatedly stressed this overarching theme: **Creating a culture of safety is both a necessary condition for addressing every challenge and the ultimate goal of improvements to ventilator technology.**

Clinical Challenges and Risks of Ventilators

Harry summarized the clinical challenges of ventilation as mortality, duration of ventilation, sedation needs, and complications. Improving patient safety and outcomes requires:

- Balancing adequate gas exchange and avoiding lung injury associated with positive airway pressure and oxygen exposure
- Minimizing the duration of mechanical ventilation with protocol-driven, spontaneous breathing trials and autonomous weaning functionality
- Improving visual and auditory alarm signal functionality
- Optimizing patient sedation and comfort
- Ambulating ventilated patients

To put the challenges into context, Harry briefly traced the history of mechanical ventilators, beginning with subatmospheric pressure ventilation, commonly known as iron lungs. Subatmospheric pressure ventilators reduce the pressure around the chest and abdomen with a vacuum pump. Large and bulky, these ventilators limited access to patients, for whom it was difficult to maintain effective ventilation. Subatmospheric pressure ventilation ushered in an innovation in healthcare—the intensive care unit (ICU), where critically ill patients could receive specialized care in specially equipped hospital areas.

Ventilator technology advanced to intermittent positive-pressure breathing, which applies pressure through an invasive endotracheal or tracheostomy tube, and to noninvasive ventilation, which uses facial masks or mouthpieces for intermittent therapy. Second-generation positive-pressure ventilators introduced more features, such as patient-triggered inspiration, positive end-expiratory pressure, and integrated monitors and alarm systems. Next-generation ventilators increased functionality with microprocessor control and more sophisticated monitoring and alarm systems—including monitoring of patient status, ventilator function, and waveforms of pressure, flow, volume, and flow—volume loops—and active valves used in continuous positive airway pressure (CPAP) ventilators.

Thanks to technology advances, ventilators now are used not just in clinical settings, but also in transport, on the battlefield, and in homes and other nonclinical settings. Many ventilators feature a variety of ventilation modes, touch-screen user interfaces that may be linked to electronic health records (EHRs) or electronic medical records (EMRs), remote reporting and remote ventilator adjustments, and multisystem, integrated monitoring. Some also use physiologic closed-loop control, which is the automatic adjustment of ventilation and oxygenation parameters in response to changes in the physiological conditions of patients.

By the Numbers

- An estimated 300,000+ patients receive mechanical ventilation in the United States every year (Centers for Disease Control and Prevention [CDC], 2014).
- Adult patients requiring prolonged acute mechanical ventilation (96 or more hours) are projected to more than double, from approximately 250,000 cases in 2000 to almost 605,900 cases by 2020 (Zilberberg et al., 2008).
- Ventilated patients are at high risk for complications, and even death. Ventilator-associated pneumonia, sepsis, acute respiratory distress syndrome, pulmonary embolism, barotrauma, and pulmonary edema are among the complications that can occur in patients receiving mechanical ventilation. Such complications can lead to longer duration of mechanical ventilation, longer stays in the intensive care unit (ICU) and hospital, increased healthcare costs, and increased risk of disability and death (CDC, 2014).
- Mortality in patients with acute lung injury on mechanical ventilation has been estimated to range from 24% in persons 15–19 years of age to 60% for patients 85 years or older (CDC, 2014).

Root Causes for Ventilator-related Sentinel Events* Reviewed by The Joint Commission 2004–2Q 2014 (n = 48)	
Human Factors	36
Leadership	27
Communication	26
Physical Environment	26
Assessment	23
Information Management	10
Special Interventions	7
Care Planning	6
Continuum of Care	6
Anesthesia Care	4

Table 1. The majority of ventilator-related Sentinel Events have multiple root causes. Source: The Joint Commission, 2014.

*Events resulting in death or permanent loss of function. Reporting of most sentinel events to The Joint Commission is voluntary and represents only a small proportion of actual events. Therefore, these root cause data are not an epidemiologic data set and no conclusions should be drawn about the actual relative frequency of cases or trends in root causes over time.

Emerging features of ventilator technology include:

- New software and functionalities
- Smaller sizes for ease of transport
- Invasive and noninvasive functionalities in a single ventilator
- Integrated oxygen blenders
- Solenoid valves, which are microprocessor-controlled valves that regulate gas flow and improve precision and flexibility of breath delivery
- New battery features for longer use life and hot-swapping, which means that batteries can be replaced during use

Advanced features can create risks, Harry said. Multiple ventilation modes can confuse healthcare providers. Vocabulary to characterize modes is not standardized. Alarm systems can cause alarm fatigue and other human factors challenges. New materials can introduce biocompatibility and circuitry issues. Portable ventilators that ease transport can create challenges with batteries, high-altitude (low-ambient) pressure, and oxygen sources.

Summit participants examined these challenges and risks, and others. The summit, held Sept. 16–17 Herndon, VA, resulted in clarion themes, challenges, and priority actions that reflect the discussions and present a framework for creating a culture of safety with ventilator technology.

Clarion Themes

1. **Create and champion standardized terminology for ventilator technology to enhance clinical information.** Coming to agreement on the language used to describe mechanical ventilation and ventilator modes will help the healthcare community improve patient safety and care.

2. **Gain consensus on biocompatibility expectations.** Clarifying expectations for biocompatibility evaluations will help industry and the FDA forge a safer, clearer, faster path to market.

3. **Strengthen clinical and technology competencies.** Requiring clinicians to demonstrate their knowledge of physiological ventilation and their skills in operating the specific ventilator(s) they use will improve patient safety and care.

4. **Advance device and system integration.** Connecting ventilators with other medical devices and systems, including integrated alarm systems, will give clinicians a more comprehensive understanding of patient conditions and enable better monitoring of and response to patient needs.

5. **Leverage human factors engineering to reduce operational complexity and enhance the safety and effectiveness of ventilators.** Attending to human factors to create intuitive, consistent user interfaces, and providing actionable clinical information, will help clinicians deliver safer patient care and track patient trends.

6. **Embrace strong and transparent cooperation, coordination, and collaboration among all stakeholders.** Creating a more transparent regulatory environment and forums for clinicians, manufacturers, and regulators to communicate and report challenges will help create a culture of safety with ventilator technology.

Top 10 Things You Can Do Now to Improve Safe Adoption and Use of Ventilator Technology

1. **Assess technology.** Conduct a technology assessment before purchasing new ventilators. Embrace simulation as a useful tool for realistic testing as part of the technology assessment.

2. **Discuss the *limits of use*.** It's just as important to discuss and assess the limits of ventilator use as it is to focus on unique and additional features of the technology. What could go wrong if a ventilator isn't used exactly as anticipated? Help sponsor ventilator testing to define the operating parameters to reasonably ensure success in field use under changing situations.

3. **Evaluate alarm system configuration.** Consider and assess an alarm signal generation delay of five to 10 seconds for those ventilators that have a delay feature. Learn more about distributed alarm systems and assess whether they could help with alarm system management.

4. **Never use ventilators straight out of the box.** Even an iPhone doesn't come straight out of the box. Assess your needs, discuss the limits of use, evaluate the alarm settings, and make the settings work for your needs.

5. **Make training matter.** *All* users should be trained before using complicated new or significantly upgraded technology such as ventilators. Use simulation for training when it's available. Clearly define roles and responsibilities of different professionals who manage ventilators and provide commensurate training.

6. **Think differently about home health use.** Start and standardize training for families within the hospital while they are still in that controlled environment.

7. **Share your competency requirements.** Automobile drivers need to show they can parallel park before getting a license. What should clinicians demonstrate before we feel safe in the field regarding ventilator technology? If you have a good set of minimum competency requirements, share them so that others can learn from them.

8. **Share lessons learned.** Manufacturers can address problems only if they know and understand them. They do care, so please share! Please also share with AAMI, so we can incorporate the lessons learned in our work with industry and healthcare delivery organizations.

9. **Standardize basic operations of ventilators.** Push harder to standardize the basic operations of ventilators across the healthcare system to lower the risk of use errors. Vary where it's essential to care, but realize that greater variation leads to a greater risk of use errors for stretched caregivers.

10. **Analyze service data.** Analyze repair and service order data to develop better preventive maintenance protocols.

Summit Overview

"Whatever our role in healthcare, one of our primary roles is to keep patients safe. We need to change the culture at the point of patients. We've got to take this on as leaders and address the clinical and technical challenges in the context of the work environment."

—Connie Barden
Chief Clinical Officer
American Association of Critical-Care Nurses

When a group of experts on medical technology gathers in a room, as they did at the AAMI/FDA Summit on Ventilator Technology, they come prepared to dive into the problems to be solved with a particular type of device they know well.

Opening presenters urged summit participants to view the challenges through a wider lens, taking into account the perspectives of clinicians, families, and patients who depend on ventilator technology in clinical and nonclinical settings.

Keynote speaker Connie Barden, chief clinical officer at American Association of Critical-Care Nurses (AACN), set the stage by imploring summit participants to resist focusing on ventilator technology in isolation. Healthcare environments are brimming with complex medical technologies. Most clinicians operate multiple medical devices, not just ventilators, and rely on them to keep patients alive, deliver patient therapy, monitor patient conditions, and inform patient care.

"This summit is so important," Barden said. "We have people here who have such huge influence on what we bring into the environment. It's really important to understand this environment." She cited several adverse events to illustrate inherent conditions in clinical environments:

- **Variations in technology, environments of care, and training.** In a neurological ICU, a 28-year-old, minimally sedated patient with an intracerebral hemorrhage showed extreme agitation and was fighting the ventilator. A respiratory therapist, floated for a night shift from a cardiothoracic ICU, made changes to the ventilator settings to improve the patient's oxygen saturation while waiting for a physician to return his call for orders. The patient then showed signs of acute barotrauma (lung injury caused by a change in air pressure) and deteriorated, nearly coding. Afterwards, the respiratory therapist stated that he "wasn't totally familiar with that vent—it's not the kind we have in our unit."
- **Alarm system management.** When a respiratory alarm signal went off in the ICU room of a 68-year-old, intubated patient, nurses on duty did not hear it because it had been turned off at the bedside. The respiratory therapist on duty was tending to another patient at the

opposite end of the unit. The patient experienced a major anoxic (oxygen deficiency) event.

- **Lack of communication, "chaos," "arrogance," and "error upon accepted error."** A healthy 11-year-old boy, Justin Micalizzi, was taken into surgery for a 10-minute procedure to drain a swollen ankle; he was dead by the next morning. "Medical care failed the family twice," Barden said, once when their son died and again when the hospital did not explain to the family what had happened. His mother, Dale Ann Micalizzi—now a patient safety advocate—blasted the healthcare system for the "chaos," "arrogance," "intimidation," lack of communication, and "error upon accepted error" that interferes with the quality of care.

Patient safety events and unintended consequences—including medication errors, wrong-site surgeries and procedures, and mishaps with medical technology—are pervasive in the healthcare environment. "More than 400,000 deaths are associated with preventable adverse events every year, making poor hospital care the third leading cause of death after heart disease and cancer," Barden said, citing statistics from the *Journal*

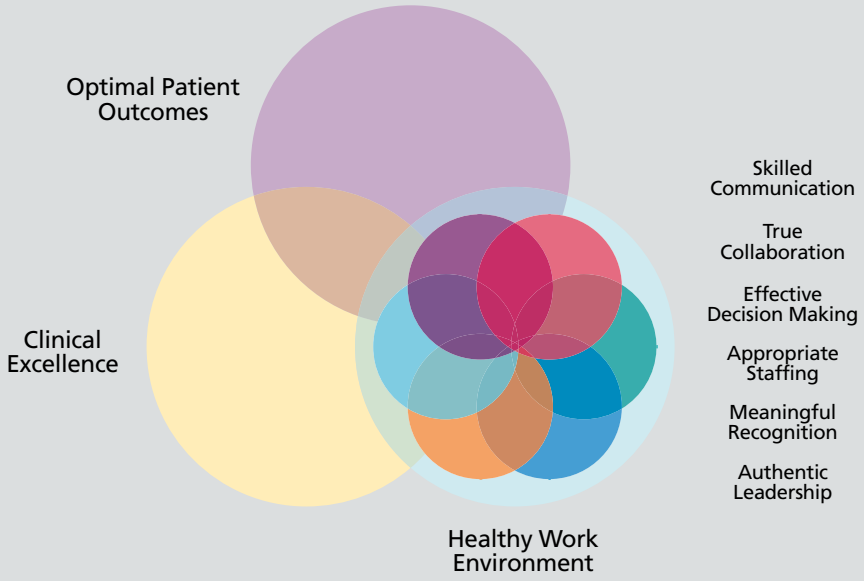


Figure 1. Requirements for Healthy Work Environments

Sources: Connie Barden. "Healthy Work Environments … Solutions Hidden in Plain Sight." The six labels on the right correspond to the six circles within "Healthy Work Environment." Presented at the AAMI/FDA Summit on Ventilator Technology, Sept. 16–17, 2014. In Maxfield et al. (2005). *Standards for Establishing and Sustaining Healthy Work Environments: A Journey to Excellence*. American Association of Critical-Care Nurses.

Standards for Establishing and Sustaining Healthy Work Environments From the American Association of Critical-Care Nurses

1. **Skilled Communication.** Team members must be as proficient in communication skills as they are in clinical skills.
2. **True Collaboration.** Team members must be relentless in pursuing and fostering collaboration.
3. **Effective Decision Making.** Team members must be valued and committed partners in making policy, directing and evaluating clinical care, and leading organizational operations.
4. **Appropriate Staffing.** Staffing must ensure the effective match between patient needs and team members' competencies.
5. **Meaningful Recognition.** Team members must be recognized and must recognize others for the value each brings to the work of the organization.
6. **Authentic Leadership.** Leaders must fully embrace the imperative of a healthy work environment, authentically live it, and engage others in its achievement.

of Patient Safety (James 2013),. Preventable adverse events in hospitals alone cost more than $17 billion a year.

Improving patient safety with ventilator technology must be coupled with attention to creating healthy work environments. "We need to change the culture at the point of patients," Barden says. "We need to take this on as leaders and address the clinical and technical issues in the context of the work environment." She offered three assertions about what that means for the healthcare community:

1. There is a direct link between work environment and patient safety. Ergo, *if you are not addressing your work environment, you are not addressing patient safety*.
2. Healthy work environments do not just happen. Ergo, *if you do not have a formal plan in place addressing work environment issues, little will change*.
3. Creating healthy work environments requires changing long-standing cultures, traditions, and hierarchies. Ergo, *while everyone must be involved in the creation of healthy work environments, the onus is on organizational, departmental, and industry leaders to ensure that it happens*.

At the urging of the AACN's 104,000 nurses, the association developed Standards for Establishing and Sustaining Healthy Work Environments, as shown in Figure 1. The standards apply to nurses, but they are just as relevant for all team members involved in patient care, including biomedical professionals, Barden said.

Communication among healthcare providers—or lack thereof—is a major issue in the healthcare environment, Barden said. Faulty communication was a root cause in 65% of 3,548 sentinel events reported to The Joint Commission between 1995 and 2005. More recently, errors in communication were identified in 2011 as a contributing root cause in 100% of all wrong-patient procedure cases in an analysis of 27,370 physician self-reported adverse events in Colorado. In 72% of wrong-site cases in that analysis, clinicians did not perform a timeout—a presurgical protocol during which the entire operating team pauses to verify the patient identity, surgical site, and procedure to be performed.

Timeouts and other safety tools, such as checklists, can help save lives and avert honest mistakes, Barden said. But a "culture of silence" impedes patient safety. An AACN report, *Silence Kills* (Maxfield et al., 2005), revealed three common, dangerous "undiscussables": dangerous shortcuts, incompetence, and disrespect. "Undiscussables represent an entrenched organizational problem," said Barden. "Organizations must overwhelm the problem of organizational silence."

Challenges in Home Environments

Ventilators used in home environments pose different sets of challenges. Unlike hospitals, homes are uncontrolled and unregulated, as shown in Table 2.

"In the patient environment, it's commonplace for ventilators to come back to us with a caramel brown tobacco sheen," said summit

"We all get tired of hearing about accidents. But we have to do something about the accidents! A culture of safety is still missing across healthcare. If we had a culture of safety, we would not be tolerating the adverse events we have every year."

—Mary Logan, President, AAMI

Variable	Hospital	Home Care
Patient environment	Controlled	Uncontrolled
Accreditation agency	The Joint Commission	Specialized—e.g., Accreditation Commission for Health Care, Inc., Community Health Accreditation Program
NFPA 99 (National Fire Protection Association Health Care Facilities Code) (2012*)	Code	No longer applicable
Inventory control	Closed system	Open system (difficult to track)
Biomedical department education levels	Associate of Applied Science (AAS) degree in biomedical equipment technology (BMET), electronics/military experience	No experience necessary

Table 2. Differences between hospital and home care. *While most jurisdictions still use the 2012 version of this code, the 2015 version is now available. Source: Donald Gillespie. "Challenges Seen in Home Care Ventilators." Presented at the AAMI/FDA Summit on Ventilator Technology, Sept. 16–17, 2014.

presenter Donald Gillespie, III, a certified biomedical equipment technician (CBET) with Advanced Home Care. "Patients on ventilators still smoke. If the medical device lets them do what they always do, they're going to do it." Cleaning ventilators between patient use is a major challenge for technicians. So is tracking the inventory of ventilators and accessories, where electronic tracking systems are not as prevalent as in hospitals.

Skill levels of service technicians who work for home care or durable medical equipment providers don't match hospital requirements either. "In home care, if you can breathe, you can get a job," Gillespie said. "You start out in the cleaning room. If you stick with it, you're doing great. In a couple of years, we'll start you working on ventilators."

Patients, caregivers, and technicians all struggle with ventilator circuits, the main line between the patient and the ventilator. "None of the circuits are the same," Gillespie said. "Ninety-eight percent of troubleshooting calls come for the circuits. The machine is extremely sensitive, but it doesn't tell you what the problem is. It could be a leak, loose connections, a kink in the line, a connection to the ventilator itself. Manufacturers sell ventilators based on patient comfort settings. The ultimate settings for the patient and caregiver would be circuit settings. If anything, manufacturers should think harder about investing in smart circuits, with a light that tells you what the problem is."

A Patient's Perspective

"Out of all the traumatic things I've had to endure, I couldn't have been more terrified than when I was on a ventilator. Yet without ventilator therapy, I would not be here today. Ventilators kept me alive."

— Stephen Mikita, JD
Assistant Attorney General for the state of Utah and an FDA patient representative with spinal muscular atrophy, a genetic neuromuscular disease

If the odds had been correct, summit presenter Stephen Mikita never would have been around to advocate powerfully for improved ventilator technology. Diagnosed with spinal muscular atrophy (SMA), the leading genetic cause of death in infants and toddlers, he has experienced countless hospitalizations and multiple bouts of pneumonia. Thanks to ventilator therapy, he is of one of the oldest survivors of SMA.

But mechanical ventilation is an "extremely terrifying experience," he said in a teleconference presentation. "One cannot overemphasize the great challenges for those of us who have been on or are on a ventilator."

Ventilated patients are vulnerable—physically challenged, emotionally stressed, and unable to communicate much, if at all. "I was unable to move my arms or hands to be able to write. So I had to communicate by blinking my eyes: one blink for yes and two blinks for no," Mikita said. "Many times during my hospitalizations, where I believe I had the capacity to provide input on my therapy, I was not given that choice. Patient choice is absolutely paramount to the decisions of this summit."

He urged summit participants to address other patient-centric challenges, including:

- Providing physicians and staff with better training in understanding vulnerable patient populations and communicating with patients
- Using tablets and other mobile devices to help patients communicate
- Keeping patients active and engaged.
- Ambulating patients who can walk
- Attending earlier to prevention of hospital- and ventilator-acquired bacterial pneumonia
- Improving access to clinical trials for patients with conditions that require ventilation
- Easing the discomfort of sterilization mouthwashes

"As you are all gathering to think about spurring innovation with ventilator technology, I hope that you will remember this if you remember anything," Mikita concluded. "One blink yes, two blinks no. I hope you will give a lot more one blinks than two blinks in developing better ventilator technology."

CLARION THEME 1

Create and champion standardized terminology for ventilator technology to enhance clinical information.

"The current state of ventilator terminology is a mess."
—Steven Dain
Associate Adjunct Professor, Electrical and Computer Engineering
University of Waterloo

Challenge	Priority Action	Accountable*
Lack of common, simple, and usable ventilator taxonomy, including nomenclature	Identify the institution(s) responsible for defining, championing, reporting, and teaching common ventilator taxonomy.	**AAMI**
	Complete ISO 19223, *Lung ventilators and related equipment – Vocabulary and semantics*, which is due for release in March 2015, and reference it in ventilator-related standards.	**ISO/TC 121/SC 4** **ISO/TC 121/SC 3**
Lack of coded terminology for communication from ventilators to ancillary systems	Once ISO 19223 is completed, incorporate standardized and simplified terminology into ventilator technology and ancillary systems.	**Manufacturers and standards-developing organizations** ISO/TC 121/SC 3 IEEE
Inconsistent understanding and use of standard ventilator terminology	Once ISO 19223 is completed, teach it, use it, and promote it.	**Academia** **Healthcare delivery organizations**
	Provide clinical and technical scenarios to demonstrate how the standard is implemented.	Professional societies Trade associations Manufacturers

*Key organizations indicated by boldface type.

Significant variation in the terminology used to describe all aspects of ventilation complicates clinical care and puts patients at risk, summit presenters and participants agreed.

Summit presenter Ronda Bradley, MS, RRT, FAARC, owner of Spiritus Consultants, exemplified this challenge with a data point: 34 different ventilators use 174 unique names for ventilator modes, according to the commonly used industry textbook, *Mosby's Respiratory Care Equipment* (Cairo & Pilbeam, 2010). In the St. Louis metropolitan region where she works, for example, five commonly used ventilators call volume-targeted pressure control ventilation by five different names and acronyms:

- CareFusion EnVe and ReVel: PRVC (pressure-regulated volume control)
- Dräger: AutoFlow
- Covidien Puritan Bennett 840: VC+ (volume control plus)
- Hamilton Medical: APV (adaptive pressure ventilation)
- GE Healthcare: PCV-VG (pressure-controlled ventilation-volume guaranteed)

"Even respiratory therapists, who, in the USA, spend 2–4 years studying respiratory care equipment, are never exposed to all of these ventilators and modes in school or on the job."
—Robert L. Chatburn (2010), Clinical Research Manager, Respiratory Therapy Department, Cleveland Clinic

Why does nomenclature matter? It's typical for different brands of ventilators to be deployed within different hospital departments and across hospitals in systems, Bradley pointed out. Clinicians who work in multiple hospital units or facilities routinely operate different ventilators. Thus, they must code-switch facilely among different ventilator "dialects"—sometimes in life-or-death situations and in the "chaotic" environments described by Barden of AACN. Transport and transitions of ventilated patients from one hospital unit to another—and to and from emergency services, long-term care units, and homes—multiply the variations in ventilators and ventilator terminology that clinicians use. Variability exists as well in the training of nurses, physical therapists, physicians, and residents, many with different specialties, to operate ventilators and understand their vocabulary.

Terminology is problematic not just in the different names and acronyms of ventilator modes, but also in different *meanings* of the same terms—and even different performance characteristics, according to summit presenter Dario Rodriquez Jr., a senior clinical/biomedical research coordinator with the U.S. Air Force School of Aerospace Medicine. "From a clinician's perspective, I like to know how a breath is being delivered and understand what I can expect from ventilators and alarms," he said. Inconsistent terminology means that isn't always a given.

For example, "on some ventilators, CMV [continuous mandatory ventilation] can be totally different modes on different ventilators," Rodriquez said. "You have the idea that it is very similar across ventilators, but in reality it reacts differently and your patient responds differently." Similarly, ventilators that use PRVC feature dual-control modes that automatically regulate pressure and volume of gas delivered to patients. But the dual controls do not necessarily operate the same way on different ventilators. Setting tidal volume, meanwhile, does not produce the same functionality on all devices. "You can't take the acronyms literally," he said. "There are differences in device performance. We need some way to tease out the differences."

Even the "ventilator" label on a device does not necessarily mean the device is a ventilator, Rodriquez added. Resuscitators are sometimes marketed as ventilators.

Like Bradley, Rodriquez called out the impact of inconsistent ventilator technology during transitions in care. From his experience in critical care transport in the military, he said that first responders spend precious time during handoffs translating ventilator information to the next round of caregivers. In addition, lack of standardized terminology and functionality complicates training. "Mistakes are more common with the introduction of new techniques," he said. "There's an increased risk of errors due to the complexity of equipment."

Now, in his work for the National Disaster Medical System at the Center for Sustain-

ment of Trauma and Readiness Skills at the Institute for Military Medicine, University of Cincinnati, Rodriquez fears similar challenges in the event of a disaster or pandemic—an unsettling prospect, given the recent public fixation on the potential for a deadly Ebola outbreak.

Clinical Documentation And Research Implications

The effects of inconsistent terminology for mechanical ventilation ripple beyond patient care. Ken Hargett, director of Respiratory Care, Pulmonary Diagnostic Services, Sleep Disorders Center and Digestive Disease Endoscopy at The Methodist Hospital (Houston), outlined these additional challenges:

- **Order entry.** Physicians, nurses, and respiratory therapists behave like polyglots when it comes to documenting mechanical ventilation. There is considerable variability in the language they use to write and chart orders, which reflects the technology and terminology with which they are familiar. "For doctors, the question is, 'What do I write?' A lot of times, there's no rate or tidal volume. Nurses say, "What's the mode, what's the rate, what's the tidal volume? We have to chart them.'" This raises another important question: "How do we understand what the ventilator is doing?" Hargett asked.
- **Legal vulnerability.** Inconsistent terminology—and fuzzy understanding of what terms on different ventilators really mean—makes healthcare systems vulnerable in litigation. "Lawyers will tear apart the clinical documentation in a chart," Hargett said. "I have seen physicians on the stand who didn't know what the ventilator was supposed to do or what to call it."
- **EMRs.** Integrating information from different ventilators that use different terminology into electronic medical records (EMRs) is proving problematic. To properly record relevant settings and patient response, each ventilator and each mode require separate entry panels in the EMR. "EMR systems don't want a page for each ventilator," Hargett said. "It's become pretty much of a nightmare."
- **Research.** Inconsistent terminology makes ventilator-related research difficult to assess and synthesize. Research literature on specific brands of ventilators uses specific terminology for modes and operations from particular manufacturers, making it difficult to compare differences in their performance and outcomes. "It's impossible for me as a decision maker to decide what to purchase," Hargett said. Tracking trends in ventilator-related patient care and outcomes is difficult for healthcare systems for the same reason. There is no consistency in ventilator-related terminology used in scholarly publications, either.

Standards on the Horizon

Ventilator terminology is on the radar screen of standards-developing organizations (SDOs). An International Organization for Standardization (ISO) subcommittee has focused on this issue since 2009, and the ISO Draft International Standard (DIS) 19223, *Lung ventilators and related equipment – Vocabulary and semantics*, will be ready for ballot in early 2015.

Summit presenter Steven Dain, Associate Adjunct Professor at the University of Waterloo and chair of ISO/TC 121/SC 4 (Technical Committee 121, *Anaesthetic and respiratory equipment*, Subcommittee 4, *Terminology and semantics*), outlined the process that has informed the standard development:

- A scientific and medical literature review
- A review of manuals and marketing materials for more than 30 ventilators
- A review of reports in the FDA's MAUDE (Manufacturer and User Device Facility Experience) database
- Informal discussions and surveys with anesthesiologists, intensive care physicians, respiratory therapists, respiratory therapist educators, and manufacturers' R&D and marketing professionals

The overarching conclusion aligns with the summit observations. "The current state of ventilator terminology is a mess," said Dain. Specifically, the ISO committee identified these needs, which are driving the standard-setting process:

- Establish a new conceptual framework that underlies advanced artificial ventilation
- Test currently used terminology against that framework

"ISO 19223 is the cornerstone of progress on several issues, such as EHR compatibility, consistent user interface, indication of mode, creating training, and training the whole ecosystem."

—Dave Osborn, Senior Manager of International Standards and Regulations, Philips Healthcare

"I had to teach 10 new surgery residents how to use mechanical ventilation technology. In the first hour, I was amazed at the misconceptions about terminology of MDs who would very soon be using this technology with patients."

—Ken Hargett
Director of Respiratory Care, Pulmonary Diagnostic Services,
Sleep Disorders Center and Digestive Disease Endoscopy
The Methodist Hospital

- Cooperate with other SDOs to have all related standards (e.g., HL7, SNOMED CT, IEEE, and IHE) use consistent terms

The objectives of the standard-in-progress are as follows:

- Start from first principles and create a patient-focused terminology with the patient seen as an independent active system
- Clearly delineate between:
  - Settings (intent): what you want the ventilator to do and how you want it to respond to the patient
  - Observations of what really happened to the patient and ventilator system of systems (may be nondeterministic based on settings)

Confusion and misconceptions about ventilator technology persist even among clinicians.

Even when the ISO standard is ratified, standardizing nomenclature across manufacturers could be a challenge, Bradley said. Manufacturers use terminology to differentiate their brands; some believe standardization will stifle innovation and oversimplify ventilation.

"This is a fabulously complex issue," she added. "But we need to start somewhere." Bradley suggested starting with primary modes of ventilation and breath type:

- VC/AC—volume-control assist-control
- PC/AC—pressure-control assist-control
- VC-SIMV—volume-control synchronized intermittent mandatory ventilation
- PC-SIMV—pressure-control synchronized intermittent mandatory ventilation
- PS-CSV—pressure support continuous spontaneous breathing
- VTPC-SIMV—volume target pressure control synchronized intermittent mandatory ventilation
- VTPS-SIMV—volume target pressure support synchronized intermittent mandatory ventilation
- APRV—airway pressure release ventilation

CLARION THEME 2

Gain consensus on biocompatibility expectations.

"Assessing risk in isolation is not enough. We must examine the whole risk–benefit environment and always compare it to real-world situations, and if decisions have to be made for a patient, consider what the patients themselves would like to decide."

— Matthew Laws
Head of TestCenter
Dräger Medical

Challenge	Priority Action	Accountable*
Lack of transparency and consistency for biocompatibility evaluation requirements for ventilator technology	Complete ISO 18562, *Biocompatibility evaluation of respiratory gas pathways in healthcare applications* (series)	**AAMI/ISO**
Inconsistent U.S. and international expectations for biocompatibility evaluations	Recognize and reference ISO 18562, which is due to be completed in March 2015	**FDA**

*Key organizations indicated by boldface type.

Industry evaluators of the biocompatibility of ventilators and ventilator accessories are experiencing an Alice in Wonderland moment. Historic industry understandings of biocompatibility requirements have been upended by a changing, and inconsistent, regulatory environment, which is creating challenges with medical device clearances and approvals, according to summit presenter Joseph Olsavsky, director of regulatory affairs with Philips Respironics.

"The FDA is enforcing a new approach in assessing the biocompatibility of air pathway materials for same-device types," Olsavsky said. "After 20+ years, this approach is inconsistent with past 510(k) submissions evaluated as skin-contacting. No industry input was sought. No scientific justification was provided."

Part of the confusion, Olsavsky said, lies in inconsistences among the recognized standards and guidance. He provided this backdrop:

- Until recently, the playbook for biocompatibility evaluations was a 1995 document, FDA Blue Book Memorandum G95-1, *Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices*.
- In 2009, ISO ratified 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*. A revised version of this standard was released in 2013. Parts 2–18 of ISO 10993, a few of which are still in development, cover toxic-specific standards for biocompatibility evaluation of hazard types (e.g., cytotoxicity, systemic toxicity).

- In 2013, the FDA released a draft guidance document, *Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,"* which was intended to interpret and clarify how the FDA is using the ISO standard. When final, this FDA guidance will supersede Blue Book Memorandum G95-1.

Olsavsky objects both to the ways in which he sees the FDA using the draft guidance and to the substance of the new requirements. He noted that the draft guidance is labeled "Not for implementation"—yet the FDA's Recognized Consensus Standard 2-156 references it as "relevant guidance" for ISO 10993-1:2009/(R) 2013.

In May 2014, Olsavsky said, four Republican members of the U.S. Senate Committee on Health, Education, Labor & Pensions (HELP) Committee sent a letter to FDA Commissioner Margaret Hamburg "to express significant concern about the [FDA's] use of draft guidances to make substantive policy changes" (FDA Law Blog, 2014). The senators assert that draft guidances are becoming default FDA policy and that the FDA increasingly regulates by issuing guidance documents, rather than through notice-and-comment rulemaking as required by the Administrative Procedure Act.

As for Olsavsky's objections to what he sees as substantive changes in FDA reviews of medical device submissions, it's important to understand that biocompatibility evaluations are meant to ensure patient safety. Medical device materials interacting with patients must work safely, as intended and designed, without causing risk or hazard. The types of direct or indirect (fluid path) contact a patient will experience, and the duration of that contact, determine the potential risks—and the types of methods and tools used for biocompatibility safety assessments. Contact types and durations are classified as follows:

Contact type
- Surface (e.g., a wound dressing)
- Externally communicating (e.g., a diagnostic catheter)
- Implant (e.g., a hip implant)

Duration
- Limited (<24 hours)
- Prolonged (between 1 and 30 days)
- Permanent (>30 days)

Historically, Olsavsky said, materials in ventilators and ventilator accessories that come into contact with patients through the gas pathway were classified as having indirect, surface contact to tissue—the lowest risk classification. Ventilator tubing was subject to general controls for Class I devices and was exempt from premarket notification procedures. Now, Olsavsksy said, the FDA has reclassified materials as externally communicating, which means that components like circuits (tubing) and masks come into direct contact with tissue inside patients through the humidified gas pathway. This is not consistent with ISO 10993, Olsavsky added.

As a result, some industry biocompatibility evaluators are reeling from FDA suggestions and requests to conduct more rigorous testing—such as acute systemic toxicity, subchronic toxicity, and genotoxicity testing, and long-term implantation studies—on ventilator-related materials, Olsavsky said.

"Other devices," including therapeutic humidifiers for home use, "are not subject to this level of testing," Olsavsky said, contending that ventilators and accessories, within their intended uses, come into contact only with skin and the mucous membrane in the air pathway, not with tissue. And ventilators are not implantable devices.

"What is the delta?" Olsavsky asked. "Are there adverse events attributed to materials? We're not seeing that. Patients are being deprived of innovative, life-saving technology."

At S^3 Challenge 2014, the FDA expressed willingness to work with industry to find solutions to biocompatibility and other challenges. The report of this March 2014 event, *A Safer, Clearer, and Faster Course to Market*, is available at www.aami.org/S3.

Regulatory Challenges With Biocompatibility

The FDA already is actively engaging with industry to inform standards development and close gaps in nonclinical biocompatibility safety tests, several summit presenters from the agency emphasized.

The FDA Responds

Following the summit, FDA presenters responded to the concerns raised by Joseph Olsavsky of Philips Respironics about perceived changes in the regulatory environment:

- "We do not agree that there has been a recent change in classification of respiratory gas pathway devices," they said, adding that there is no prior FDA determination or publication that can be cited to support the statement that there was a prior classification of these devices as surface-contacting.

- "We do not agree that the FDA has been implementing the 2013 draft guidance document, *Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*." We have historically cited and continue to cite the 1995 G95-1 Blue Book Memorandum tests for consideration during the biocompatibility review of these devices and will do so until such a time as the new guidance is finalized.

- "We acknowledge that there may have been some inconsistency in the past and recognize the need to have clear guidance to industry. We have been actively engaged with industry in the development of standards related to biocompatibility of gas pathway devices since the origination of these standards in 2012."

Summit presenter Rakhi M. Dalal, toxicologist with the FDA CDRH Office of Compliance, Division of Manufacturing and Quality, shared the regulatory classification of gas pathway devices showing the risk-based paradigm for medical devices that contact the gas pathway, as shown in Table 3.

"Early safety evaluations are done through nonclinical tests—engineering, mechanical, biocompatibility, residual release—and clinical and other methods as applicable to the intended use and exposure type and duration of the medical device contacting the gas pathway," Dalal said. She shared the FDA's regulatory principle: "Get medical devices (containing gas pathway) which have a reasonable assurance of safety and effectiveness to market as efficiently as possible." (See the sidebar on page 21, "Biological Safety Considerations: What the FDA Wants to See," for specific criteria for safety evaluations.)

Dalal reiterated that current biocompatibility evaluations are performed as per G95-1 FDA Blue Book Memorandum and ISO 10993-1 recommended tests. She also acknowledged that challenges exist with these tests, as they have limitations in addressing biological safety of certain components of gas pathway devices. Some of these challenges include:

- Mapping the circuitry in reference to the patient (i.e., upstream, downstream, dry or wet gas pathway)
- Appropriateness of the current battery of ISO 10993-1:2009 tests for the safety evaluation of the device gas path
- Appropriateness of extractables and leachables study for the safety evaluation of the gas/air/condensate component of the device

Dalal explained that current challenges are being discussed with the ISO/TC 121/SC 3/WG 13 subcommittee—ISO 18562-1, -2, -3, and -4, *Biocompatibility evaluation of respiratory gas pathways in healthcare applications*. These challenges were the main focus in a TC 121/SC 3/WG 13 meeting in South Korea in June 2014, she said, and acknowledged the summit presentation of Matthew Laws of Dräger Medical on the progress on this standard. She summarized the following ways in which the FDA is engaging with industry to address the potential gaps and challenges in gas pathway devices:

- Use of International Standard ISO-10993, *"Biological Evaluation of Medical Devices Part 1: Evaluation and Testing": Draft Guidance for Industry and Food and Drug Administration Staff* (April 23, 2013) (public comments under evaluation)
- Biological safety tests relevant to containing gas path—ISO/TC 121/SC 3/WG 13, *Biocompatibility evaluation of respiratory gas pathways*, is working on the ISO 18562

"The FDA continues to encourage the industry to participate in the gas pathway standards to effectively communicate on addressing concerns related to biocompatibility of gas pathway devices."

— Rakhi M. Dalal, Toxicologist, CDRH Office of Compliance, Division of Manufacturing and Quality

Category	Class I (low risk)	Class II (medium risk)	Class III (high risk)
Examples	21 CFR 868.5280, JAY, support, breathing tube 21 CFR 868.5220, BYO, Bottle, Blow	21 CFR 868.5895, Continuous ventilator 21 CFR 868.5905, Noncontinuous ventilator	High-frequency ventilator, LSZ
Regulatory Controls	General controls GMP nonexempt GMP exempt	General controls Special controls	General controls Premarket Application

Table 3. Medical devices contacting gas pathway: regulatory classification. Devices are classified and regulated according to their degree of risk to the public. Abbreviations used: CFR = Code of Federal Regulations; GMP = Good Manufacturing Practices; JAY, BYO, LS = product codes.
Source: Rakhi M. Dalal. "Biocompatibility Evaluations of Medical Devices Contacting Gas Pathway." Presented at the AAMI/FDA Summit on Ventilator Technology, Sept. 16–17, 2014.

series of standards, *Biocompatibility evaluation of respiratory gas pathways in healthcare applications*

A New Standard in the Works

Summit presenter Matthew Laws, head of TestCenter, Dräger Medical, explained the new series of standards in development, ISO/CD 18562, *Biocompatibility evaluation of respiratory gas pathways in healthcare applications*. The standard is intended to result in:

- New test methods where chemical analysis is preferred
- Justifiable allowable limits for substances in the airstream
- Repeatability and certainty to manufacturers, test houses, and regulators
- Significant reductions in animal testing and the time required for testing

These ventilator-specific draft standards, which are due to be released in March 2015, address the detection of contaminants in the gas that reach the patient. "What is truly important is what gets to the patient," said Laws, who is heading the development of these standards. (Anything that physically touches the patient, such as tubing and masks, would still be subject to ISO 10993). ISO 18562 has four parts:

- Part 1: Evaluation and testing within a risk management process (general requirements)
- Part 2: Tests for emissions of particulate matter
- Part 3: Tests for emissions of volatile organic compounds (VOCs)
- Part 4: Tests for leachables in condensate

Part 1 hews closely to ISO 10993 in providing a guide to the development of a biological evaluation plan to be carried out as part of an overall risk management process. This part sets up the specific tests detailed in parts 2, 3, and 4. "The suite of tests should not be used as a checklist—'do all'—but as a framework—do what is necessary," Laws said.

Parts 2 and 3 present test methods and allowable levels of particulate matter and VOCs that arise from surfaces of breathing gas pathways. Part 4 presents test methods and guidance on how to assess allowable levels of contamination that may arise from condensate on the surfaces of breathing gas pathways, and subsequently enter the patient. "Allowable levels" focus on:

- Known substances from known inhalation studies

"Clearly we need a laser-like focus on accelerating the completion of both the ISO 18562 series (biological evaluation of gas pathways) and ISO 19223 (taxonomy). Whatever we can do to get these draft international standards to the Central Secretariat as soon as possible is very, very important. They are all on the critical path to the future."

—Dave Osborn, Senior Manager of International Standards and Regulations, Philips Healthcare

Figure 2. Toxic volatile organic compounds (TVOCs) from medical devices in contact with breathing gas. Source: Matthew Laws. "Biological Evaluation of Medical Devices in Contact with Breathing Gas." Presented at the AAMI/FDA Summit on Ventilator Technology, Sept. 16–17, 2014.

- Known substances for which there is not sufficient information
- Unknown substances

Allowable limits are a sticking point. ISO/TC 194—the technical committee on biological and clinical evaluation of medical devices—suggests assuming all unknown substances, and known substances for which there is not sufficient information, are extremely toxic and setting an allowable limit of a few micrograms a day. "This is extremely low—and it is not possible to manufacture medical devices or accessories to meet this limit," Laws said. "The suggested allowable levels are based on very conservative assumptions—such as an increase in cancer in one of 100,000 people for a 70-year exposure."

Everything has a risk associated with it, including seat belts, air bags, crash helmets, aspirin, antibiotics, and any medical procedure, Laws noted. It's important to balance risk with benefits. By way of example, he presented results from some 1,000 toxicity tests from various medical device manufacturers and compared them with similar toxicity results from automobiles and buildings, as shown in Figure 2.

A joint meeting between TC 194 and a working group of TC 121, the ISO technical committee on anaesthetic and respiratory equipment, was scheduled for December 2014 to resolve the allowable limits issues.

FDA PERSPECTIVE

Regulatory History, Considerations, and Challenges

Summit presenter Amy LeVelle
Biomedical Engineer and Premarket Reviewer
FDA CDRH Office of Device Evaluations

The FDA historically has considered respiratory devices that indirectly contact the patient gas pathway to be categorized as externally communicating devices with tissue contact and has recommended biocompatibility testing in accordance with the ISO 10993 series and the FDA G95-1 Blue Book Memorandum. There has been no recent reclassification related to these devices. The FDA has a long history of asking questions related to externally communicating devices in the respiratory gas pathway.

The FDA's consideration of these devices as externally communicating was first published almost 20 years ago in the 1995 Draft Ventilator Guidance. The FDA does not implement draft guidance. However, draft guidance often reflects the current policy at the time. This contact category is also consistent with the consensus of the international community as indicated by FDA-recognized standards, such as ISO 17510-2 (2007) for CPAP equipment, which states that gas pathway materials will be evaluated as externally communicating and comply with the ISO 10993 series. Current recommended tests for consideration based on this contact category have been communicated in the FDA G95-1 Blue Book Memorandum, which is unchanged since 1995.

Why Does the FDA Consider Gas Pathway Devices as Externally Communicating?

The FDA believes these devices have the potential to leach substances into the patient airway and lungs, which may lead to unanticipated health consequences in an already vulnerable respiratory population. This could lead to inflammation or worsening of the respiratory ailment. In addition, as the lung is highly vascularized tissue, there is an increased concern of systemic toxicity, particularly considering the long-term use of many of these devices.

What Is the Problem?

The current industry standard, ISO 10993, does not address gas pathway devices and only limited guidance from the FDA is currently available. New guidance and standards are needed to address this gap and provide clear communication of biocompatibility recommendations to the industry.

What Are the Most Common Issues in Premarket Submissions?

These are a few of the most common issues encountered during premarket submissions, which may be important for manufacturers to consider in preparing these submissions:

1. Identification of the Patient Contact Category and Exposure Duration

The FDA does consider respiratory devices as externally communicating. Some submissions may consider only whether there is direct patient contact and do not consider modes of indirect contact through the gas pathway. Manufacturers should consider both direct and indirect modes of patient contact through the gas pathway in determining whether biocompatibility testing may be needed.

Another concern is that there may be no consideration for cumulative exposure to a device. Although a device may not continu-

"Materials certification should be identical in formulation and processing."
—Amy LeVelle

ously contact the patient, it still may be considered as permanent in duration if it has daily or repeated exposure to the patient. This includes consideration for repeated use of disposable devices.

2. Materials Certification
Manufacturers often cite predicate devices, which they claim to have similar materials. It is difficult for the FDA to be able to evaluate the biocompatibility and quantify the differences in materials that are only considered to be similar. There are often differences in the formulation, additives, and plasticizers used in the manufacturing process, as well as postmanufacturing residuals. Differences in the processing may drastically alter the material properties and affect the leachability of chemicals from the device. It is important to take into consideration the effect of the device as a finished product.

Certification statements are also sometimes submitted declaring identical materials and processing to a predicate device from a different manufacturer. However, in most circumstances it would not be appropriate to make such a statement requiring detailed knowledge of the predicate manufacturing. It is therefore important to provide a certification statement from a party appropriately able to make the statement.

3. Humidified Air vs. Dry Gas Pathways
Manufacturers must consider how materials will react in a dry environment compared to the heated and humidified environment used to deliver gas through ventilators and accessories. Regarding components that may be in contact with humidified air (including patient rebreathed air) or aerosolized drugs, there could be an increased risk of leaching of materials used in ventilators. Therefore, the FDA typically recommends all the ISO 10993 tests for consideration as identified in the FDA G95-1 Blue Book Memorandum. For components that are in contact only with the dry gas pathway, the FDA typically recommends testing for volatile organic compounds (VOCs) and particulate matter to ensure the device does not contaminate the air quality emitted by the device. Manufacturers also should consider including a diagram of the humidified and dry gas pathway.

4. Accessories
Biocompatibility evaluation may not always include evaluation of all accessories included with the device. It is important to clearly identify all accessories and how these have been evaluated. If prior 510(k) clearance was granted for any accessories, this should be clearly identified.

5. Biocompatibility Test Reports
In many cases, manufacturers submit testing conducted on raw materials as opposed to the final finished device. This can be problematic, as the biocompatibility evaluation must consider the final finished device. In other cases a different test article may have been used in the test reports from the 510(k) device or the test article may not be identified at all. There should be clear identification of the test article and how it relates to the device under review in the 510(k) submission.

The extraction conditions and sample preparation are also very important considerations. Poor sample preparation can completely invalidate test results, requiring testing to be repeated. The FDA recommends careful consideration of extraction conditions and sample preparation, including consideration of worst-case conditions of device use and following ISO 10993-12.

Biological Safety Considerations **What the FDA Wants to See**

Final device description
- Components/accessories and patient contact (direct/indirect through air/gas/condensate/dry gas)
- Final device material composition, such as surface property (corrugated or smooth), sterile/nonsterile, single or multiple patient use, single use or reprocessed

Circuit map relative to patient Indications for use/intended use
Proposed population (e.g., vulnerable populations such as neonates and pediatric)

Biological safety evaluations nonclinical testing—biocompatibility evaluations per:
- FDA Guidance: *Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing*, 1995
- ISO 10993, *Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process*, 2009
- Quality of air/gas/condensate/dry gas to the patient

Clinical evaluation as applicable

Source: Rakhi M. Dalal. "Biocompatibility Evaluations of Medical Devices Contacting Gas Pathway." Presented at the AAMI/FDA Summit on Ventilator Technology, Sept. 16–17, 2014

CLARION THEME 3

Strengthen clinical and technology competencies.

"Training ought to be measurable, goal-oriented, consistent, recorded, practiced through a practicum, and testable for retention and training competency, with continuous quality control auditing. Partner with industry to develop clinician curricula so ventilators will be used appropriately."

—Robert Kopotic
Senior Director of Clinical Affairs
CAS Medical Systems Inc.

Challenge	Priority Action	Accountable*
Inconsistent education and training for the diverse range of clinicians and others who use ventilator technology	Identify the top 10 competencies required by key users of ventilator technology, including: • Physicians • Respiratory therapists • Nurses • Emergency medical technicians and paramedics • Healthcare technology management professionals • Caregivers • Patients	**Manufacturers** **Healthcare delivery organizations** All specialty and ventilation-related professional associations
	Standardize training.	**AAMI** **Manufacturers**
Uneven clinical and technology competencies	Prohibit any clinicians from using a ventilator on which they have not been trained.	**Healthcare delivery organizations**
	Provide standardized and ongoing education, training, and competency testing to all clinicians who use ventilator technology.	**All specialty and ventilation-related professional associations** **HTSI**
	Require clinicians to earn certification, based on the level of demonstrated competencies, in the use of ventilator technology.	**Healthcare delivery organizations**
Complexity of patient–ventilator interactions	Teach clinicians what ventilation technology does as well as how to think critically to attend to the particular needs and problems of ventilated patients.	**Clinical educators** **Academic institutions**

*Key organizations indicated by boldface type.

Too much training to use medical technology focuses on "knobology"—industry lingo that means knowing how to work knobs or dials on devices or, more commonly these days, touch-screen user interfaces.

That narrow "how-to" training to operate ventilator technology simply isn't good enough anymore. Clinicians also need to know "why to" and "when to" ventilate particular patients—and how to troubleshoot quickly when necessary. They need to know which of any of the dozens of ventilator modes on a typical ventilator, and especially the particular ventilators they use, will safely and effectively meet patient needs.

Summit presenters and participants advocated for more consistent, standardized, and robust training in the use of ventilator technology, focused on building key competencies and differentiated by clinical role. Clinicians should be required to demonstrate their competencies as well; "seat time" in training is no guarantee of competency. Clinicians with demonstrated competencies should be rewarded with certification, with levels from basic to advanced. Sustained, job-embedded training in smaller doses over time, rather than one-shot sessions, would be most effective.

What Do Clinicians Need to Know And Be Able to Do with Ventilators?

"The patient–ventilator interaction is one of the most complex interactions you'll ever encounter," said summit presenter Cyndy Miller, clinical marketing manager at Covidien. "Ventilators have millions and millions of lines of code. Our screen interactions are much more complex than on ventilators that were knob-driven."

Given this complexity, "there appear to be some gaps in our training systems," Miller said. "Closing the gaps may improve the safety of care."

So what do clinicians need to know and be able to do with ventilator technology? Miller outlined these typical healthcare facility needs:

- Why and when to ventilate
- "Knobology," including the "geography" of the touch-screen hardware and "mapping" of the software navigation
- Proper setup of ventilation, monitoring, and alarm conditions
- Functionality and application of typical mode and breath types
- Analysis of ventilation monitoring information and graphics
- Reprocessing of equipment between patients
- Evidence-based research about current trends in ventilation
- Product use competency

Critical care clinicians also should have practical knowledge of the physiology of respiration and the potential physiological hazards of mechanical ventilation, according to summit presenter Robert Kopotic, senior director of clinical affairs at CAS Medical Systems Inc.

"We may be expecting our therapists to do too much with the training they get. It's not only about knowing which knob to press, it's about knowing the patient problems you are trying to solve and how to use the technology as a tool to do it."

—Cyndy Miller,
Clinical Marketing Manager, Covidien

Training should cover fundamentals, such as: "What is a breath? What causes our need to breathe? There are two facets to that—external and internal respiration. What are the results of internal and external respiration? We are focused on how we can force a breath in, how much oxygen to give a person, and then dealing with holding it in by measuring blood gas levels of internal respiration." It's equally important to understand how carbon dioxide (CO_2) is created at the metabolic level and expelled—or not. "CO_2 is the marker of ventilation," Kopotic said.

Lab study is ideal for building applied knowledge and skills that can be transferred to clinical care without compromising patient safety, Kopotic said. High-frequency ventilation, for example, presents special training needs. Lab training can help clinicians minimize risks to patients by:

- **Reducing lung injury.** Ventilators that deliver large tidal breaths can cause lung injury. Clinicians need to know how to avert lung injury—and they can learn that by studying respiration in other animal species. High-frequency oscillatory ventilation mimics how dogs pant (at a frequency of 3

"Training should be mandatory for all clinicians before they touch a piece of complex technology."

—Mary Logan,
President, AAMI

Hz, or cycles per second) and how hummingbirds beat their wings in flight in very fast pulses (at 50 Hz). "You can take these devices and show how you can mimic how a hummingbird is able to get the gas out, and transfer that to a patient," Kopotic said.

- **Reducing noise on the neonatal unit.** High-frequency ventilators can more than double the noise levels in neonatal units, which is stressful and can have detrimental effects on babies and staff. Clinicians can learn about the physical properties of sound—and how to apply noise abatement methods.
- **Clearing patients' lungs.** High-frequency ventilation can lead to accumulation of mucus in the airway, which can trap CO_2 there. Clinicians need to know how to palpate and visualize the lungs of ventilated patients and heighten pulmonary hygiene.
- **Providing high humidity.** Dangerous levels of CO_2 can build up in patients on high-frequency ventilators. Clinicians need to learn the best ways to highly humidify patients, who need moisture along the airway to enhance CO_2 exhalation.

Clinicians also need to understand the relationship between ventilation and brain injury, Kopotic said. Inadequate oxygen levels and dramatic changes in CO_2 levels during mechanical ventilation can cause brain damage.

"The typical facility needs regularly reinforced, titrated levels of job- and role-specific information."

—Cyndy Miller, Clinical Marketing Manager, Covidien

Training Principles To Support Safer Clinical Care

According to Robert Kopotic of CAS Medical Systems Inc., although training principles are well understood by educators,they have not been formalized for clinician traning. Training principles should:

- Be measurable
- Be goal oriented
- Be consistent
- Be recorded
- Be testable (for retention), with training competency and continuous quality improvement (CQI) auditing
- Be practiced through a practicum—simulation vs. human/nonhuman direct application
- Include partnerships with industry for clinician curricula

Barriers to Effective Training

From a manufacturer's perspective, lack of incentives and institutional support impact both clinicians' participation in product training and the quality of the training, Miller said. Hospitals may not pay employees to attend product training; therefore, employees may not attend, she said. If training is held during clinicians' shifts, attendance and attention depend on their workloads, which often means distracting interruptions. The time allotted for product training is typically one hour or less. This allows time to cover "knobology"—and nothing else.

"Manufacturers know the information that hospitals need for safe clinical application of high-technology products," Miller said. "Manufacturers have the ability to instruct operators on the safe and effective use of our products," typically with hands-on training and digital assets for independent, self-paced study. However, "in-servicing may fall short of meeting the training goals if the training is too short, or if there is too much, too soon."

Manufacturers also can provide some, but not all, training-related "wants" requested by typical healthcare facilities, as shown in Table 4.

The Case for a Culture of Continuous Learning

Summit presenter Mary Logan, JD, CAE, AAMI president, advocated for cultural changes in clinicians' training. Inspired by a training event and survey by the Anesthesia Patient Safety Foundation (APSF), she takes the strong stance that training should be mandatory for all clinicians before they touch a piece of complex technology. She made these points to back this assertion:

Healthcare is a complex, sociotechnical system characterized by:

- **Overload.** Clinicians deal with "alarm overload," features upon features in proprietary electronics with no design standardization, and "shiny object syndrome"—an appetite in healthcare systems for the latest medical equipment.
- **Accidents.** Healthcare costs account for more than 17% of U.S. GDP, but the United States is only 37th in healthcare quality. There are 100,000 to 200,000 preventable healthcare deaths every year—the equivalent of two 747s colliding daily.

But because these deaths occur one by one, the healthcare community and the public aren't paying enough attention to them.

- **Integration.** Everything is being integrated—medical devices and systems, information technology systems, EMRs and EHRs. Yet healthcare has a dispersed regulatory scheme and no systems integrator safeguarding patients and clinicians.

The culture of training in healthcare is highly variable. Variations in clinical workflow, learning cultures of clinicians, and hospital philosophies about training contribute to uneven training. With no systems approach or integrator, training occurs in isolation, with inconsistent scope of authority and accountability.

Only a culture of continuous learning can improve patient safety. Clinicians need a continuous feedback loop to learn from adverse events and near misses. The reality is that variations in practice and settings, and a fear of liability, prevent continuous learning from happening.

Logan closed her presentation with this food for thought:

Why Do We Need Training Standards?

- For consistency
- For simplicity
- To overcome barriers
- To measure success

What Do Training Standards Need to Cover?

- Content
- Assessment
- Trainers
- Evaluation
- Details
- What is success?

What Do Anesthesia Professionals Say About Training?

- 97% agree that competence should be confirmed.
- 95% agree that technology training elements should have standardized elements across venders.
- 84% agree that clinicians should maintain their certification with technology training and competency assessment on the use of advanced medical technology.
- 77% agree that advanced troubleshooting simulation should be a mandatory component of training.
- 65% say the traditional in-service training model (which occurs when equipment is installed, is voluntary, and is offered during clinical work hours) is inadequate and needs to be replaced with new concepts/technology such as e-learning modules, hands-on simulation sessions, and individual downloadable apps.

Source: Paulsen & Morell, Anesthesia Patient Safety Foundation, 2013

Healthcare Facility Training "Wants"	Can Manufacturers Provide This?
Food and drinks for product training participants	Yes, within reason. (Sunshine laws require full reporting by manufacturers of all health care professional [HCP] expenses.)
Continuing education (CE) hours for time spent in product-specific, in-service training	No product-specific CE hours. (Generic CE hours are sometimes possible.)
Direct or indirect support (e.g., cash, gift cards, tickets to events, sponsorship of Respiratory Therapy Week or golf events)	No
Instructions about off-label product use	No
Extended loan of equipment	Yes, for up to 120 days, if warranted
Confirmation of clinicians' competency on product use	No. (Manufacturers can help facilities develop their own competency requirements.)

Table 4. Healthcare facility training "wants" vs. what manufacturers can provide. Source: Cyndy Miller. "Training: What's Needed to Support Safer Clinical Care." Presented at the AAMI/FDA Summit on Ventilator Technology, Sept. 16–17, 2014.

CLARION THEME 4

Advance device and system integration.

"Data communication failures are an increasing issue."
—Shelly Crisler
Biomedical Engineer
Center for Engineering and Occupational Safety and Health
Department of Veterans Affairs

Challenge	Priority Action	Accountable*
Connecting ventilator technology with other devices and systems to monitor patient conditions and collect patient data comprehensively	Better integration of all ventilators to patient monitors, other medical devices, and electronic medical and health records (EMRs and EHRs).	**Manufacturers** **IT providers and vendors** **ASTM-OpenICE** MDPNP TATRC
	Demand interoperability in products.	Healthcare delivery organizations and other purchasers
Alarm system management, including alarm condition burden, alarm fatigue, alarm signals, complex middleware, and lack of actionable information from ventilator alarm systems	Develop a clear understanding of the requirements for standardization and customized packages for visual alarm signals (messages) to users.	**AAMI** **IEC/62A** **ISO/TC 121/SC 3** **OpenICE**
	Improve alarm system communication. Use open-source, standards-based, nonproprietary middleware for medical device interoperability and distributed alarm systems.	**Manufacturers**
	Translate alarm conditions, priorities, and actions for clinicians. Use IEC/TR 80001-2-5, *Application of risk management for IT-networks incorporating medical devices: Application guidance—guidance for distributed alarms*	Healthcare delivery organizations Vendors
Lack of coded terminology for communication from ventilators to ancillary systems	Complete and use ISO 19223, *Lung ventilators and related equipment — Vocabulary and semantics*, and reference it in ventilator-related standards.	**AAMI/ISO** **FDA** **Manufacturers** **OpenICE** **IEEE**

*Key organizations indicated by boldface type.

Ventilators are sophisticated, self-contained systems in their own right. By and large, ventilators work well on their own, with notable exceptions. Within the healthcare environment, however, ventilators are part of a "system of systems" in which many systems make up a holistic system that is greater than the sum of its parts. Ventilators do not always play well with other systems—and that's a drawback.

Ventilators get many things right, said summit presenter Brad Bonnette, health devices product engineer, ECRI Institute, including:

- Advanced modes and features, with innovations such as touch screens and graphical depictions of the lungs
- Reliability and safety—ventilators are workhorses that don't fail often
- Self-tests to find problems before they are deployed and before they fail

But connecting ventilator technology to networks and integrating information from ventilators into other systems, such as EMRs or EHRs and physiological monitors, can be a challenge, summit participants said. Other systems could use data captured by ventilators to provide clinicians with comprehensive, aggregated information about patients' status in real time. Resolving interoperability challenges and improving decision support systems would empower clinicians to deliver better patient care.

Lack of standardized, coded ventilator terminology and data communication protocols for seamless communication with ancillary systems is holding back progress. Indeed, "data communication failures are an increasing issue," said summit presenter Shelly Crisler, a biomedical engineer at the Department of Veterans Affairs (VA) Center for Engineering and Occupational Safety and Health.

To learn more about device and system integration, see the report of the 2012 AAMI/FDA Interoperability Summit, *Medical Device Interoperability: A Safer Path Forward*.

Perennial Challenges With Alarm Systems

Clinical alarms are a flashpoint with ventilators, as they are with many medical devices. Again, alarm systems in ventilators incorporate some features well, Bonnette said, including:

- Default alarm parameters
- Settings to adjust alarm parameters for individual patients
- Mechanisms to prevent unintended alarm settings
- Logs

"Modern ventilators are amazing devices that help patients better than ever before. As good as they are, they can be a lot better."

—Brad Bonnette,
Health Devices Product Engineer,
ECRI Institute

Bonnette cited these challenges with ventilator alarm systems:

- Alarm systems do not always do a good job of notifying clinicians when they need to intercede. "VENT alarm" is not actionable information, he said.
- Distinguishing between alarm signals that indicate life-threatening and "nuisance" alarm conditions is difficult.
- Alarm signal delays are not adequate.
- Screen displays for alarm parameters and disabled settings are not adequate.
- It is too easy to set alarm limits and parameters incorrectly.
- It is difficult to communicate alarm messages to clinicians, particularly if clinicians are not at the patient bedside, via a nurse call system or distributed alarm systems.

"Most third-party integrators do not deal with alarm systems," Bonnette said. "If you want to integrate alarm systems with physiological monitors, you basically have one choice. That's not good enough."

Resources for Clinical Alarm Management

- *Clinical Alarms*, the report of the 2011 Medical Device Alarm Summit convened by AAMI, the FDA, The Joint Commission, the American College of Clinical Engineering, and ECRI Institute (**www.aami.org/publications/summits/2011_Alarms_Summit_publication.pdf**)
- Subsequent efforts by the *AAMI Healthcare Technology Safety Institute* to address alarm-related challenges (**www.aami.org/htsi/alarms/index.html**)

Leading Practices on Ventilator Alarm Management

THE JOHNS HOPKINS HOSPITAL

To address alarm fatigue and alarm burden in ICU settings, The Johns Hopkins Hospital in Baltimore, MD, conducted a study to evaluate the frequency and duration of mechanical ventilator alarm signals and appreciate the impact of alarm duration on practitioners' response to them. As a result, the hospital instituted a five-second delay on alarm signal generation.

Summit presenter Matthew P. Trojanowski, manager of Adult Respiratory Care Services at the hospital, summarized the institutional review board–approved study (Trojanowski, Dela Paz, & Cvach, 2014). During a 10-week period, the study team collected data on the average number of alarm conditions per ventilator per day and average alarm condition duration from medical, surgical, and neurosurgical ICUs. Over that time, more than 27,600 distinct ventilator alarm conditions were captured from those three ICUs. About 64% of these alarm conditions lasted five seconds or less, as shown in Table 5.

The study team also surveyed 539 respiratory technicians and asked, "How likely are you to respond to an alarm signal lasting less than five seconds?" Eighty percent of them responded "not likely" or "somewhat likely," as shown in Figure 3. By delaying the alarm signals from these short-duration alarm conditions, the hospital reduced the average number of alarm signals per ventilator per day from 16.15 to 5.81, as shown in Figure 4.

"What we've learned is that the majority of ventilator alarm conditions are single instances of less than five seconds," Trojanowski said. "The ability to respond to or intervene for alarm conditions of less than five seconds in duration is limited. A significant number of ventilator alarm signals could be eliminated with implementation of a five-second delay.

"If we had a simple five-second alarm signal delay, similar to physiological alarm signals for oxygen saturation, we're talking about a significant reduction in nonactionable alarm signals."

—Matthew P. Trojanowski, Manager, Adult Respiratory Care Services, The Johns Hopkins Hospital

Total Number of Mechanical Ventilator Alarms	Frequency of Alarm Signals per Ventilator per Day		Alarm Signal Duration		
27,607	Mean	Median	Mean(s)	Median(s)	Percentage <5 Seconds
	16.15	15.85	6.62	3.97	64.03

Table 5. Data on the number, frequency, and duration of mechanical ventilators in three ICUs. Source: Matthew P. Trojanowski. "Characterizing the Frequency & Durations of Mechanical Ventilator Alarms in the ICU." Presented at the AAMI/FDA Summit on Ventilator Technology, Sept. 16–17, 2014.

HOW LIKELY ARE YOU TO RESPOND TO AN ALARM SIGNAL LASTING LESS THAN FIVE SECONDS?

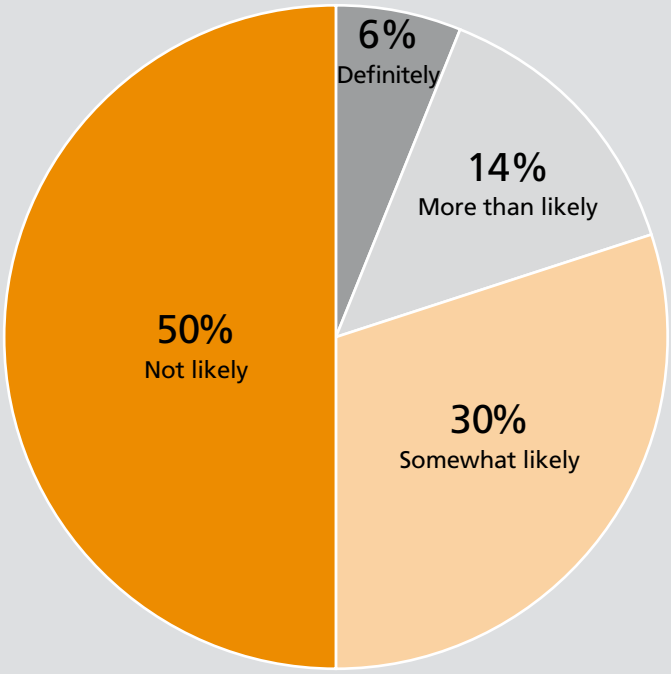


Figure 3. Respiratory therapist responses. Source: Matthew P. Trojanowski. "Characterizing the Frequency & Durations of Mechanical Ventilator Alarms in the ICU." Presented at the AAMI/FDA Summit on Ventilator Technology, Sept. 16–17, 2014.

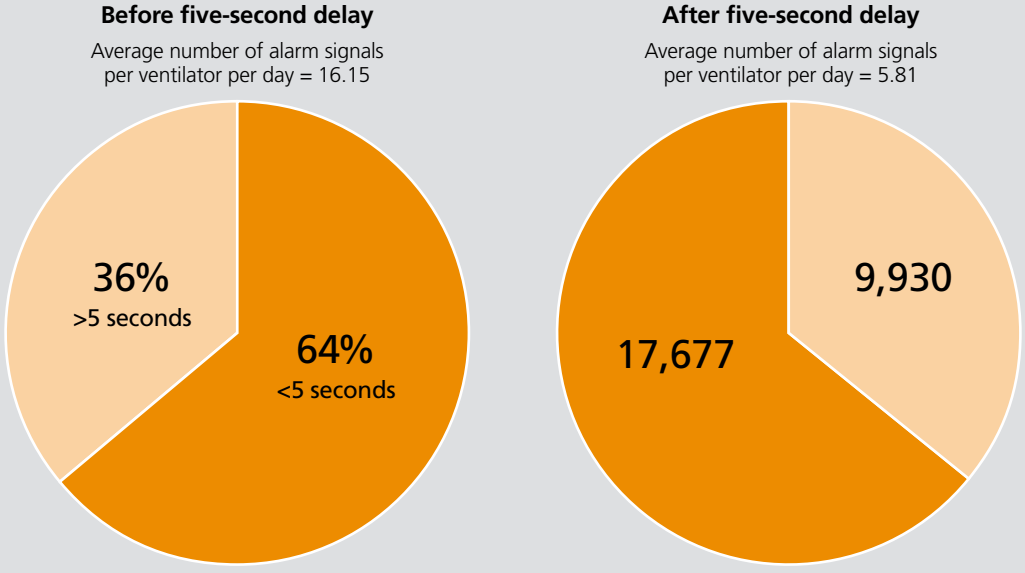


Figure 4. Data showing that a five-second delay significantly reduces alarm signals in the ICU setting. Source: Matthew P. Trojanowski. "Characterizing the Frequency & Durations of Mechanical Ventilator Alarms in the ICU." Presented at the AAMI/FDA Summit on Ventilator Technology, Sept. 16–17, 2014.

CLARION THEME 5

Leverage human factors engineering to reduce operational complexity and enhance the safety and effectiveness of ventilators.

"We want devices that are as capable as they can be, but not so complex that people can't figure out how to use them."

—Dario Rodriquez Jr.
Senior Clinical/Biomedical Research Coordinator
U.S. Air Force School of Aerospace Medicine

Challenge	Priority Action	Accountable*
Complex and inconsistent ventilation technology, which can make it difficult to use and can compromise patient care and safety	Make ventilators intuitive for clinicians and other users to set up and operate, regardless of the make, model, and ventilation mode.	**Manufacturers**
Mismatches between ventilator technology and its clinical uses, use environments, and users	Use human factors approaches to design, test, and create ventilator technology with more consistent user interfaces. Take into account different use scenarios, use environments, and user needs.	**Manufacturers**
Increasing number and complexity of ventilation modes	Identify a clear, component-level path for the development and implementation of physiologic closed-loop systems that support patient safety and evidence-based clinical practices for ventilation.	**Manufacturers FDA ISO/TC 121 and IEC/62A**
Lack of useful clinical information from ventilator technology	Make patient and ventilator information available in consistent format to enable clinicians to deliver better patient care and track trends.	**Manufacturers Healthcare delivery organizations**

*Key organizations indicated by boldface type.

The Holy Grail for ventilator technology, as with other complex medical equipment, is advanced functionality that is safe, reliable, consistent, and intuitive for clinicians to use in the environment of care. Summit presenters and participants identified both barriers and potential solutions—including human factors design, simulations, usability testing, rapid feedback, risk analysis and management, and quality systems and controls—to address this conundrum.

The VA has been culling patient safety reports from its National Center for Patient Safety (NCPS) and service histories to understand use issues related to ventilators, according to summit presenter Tandi Bagian, director, Human Factors Engineering Division, Veterans Administration (VA) NCPS. Some 1,200 self-reported events or problems involving ventilators since October 2006 were categorized into six major categories of use issues, as shown in Table 6.

The VA has developed a Patient Safety Strategic Road Map that situates humans as part of a system; takes into account user experiences for purchasing, integration, and training; and analyzes the environmental, human, and task elements to identify avenues for improvements in ventilator safety.

This focus on ventilator technology is part of a VA/FDA collaboration to advance the ability to learn from adverse events. Use issues with defibrillators and electrosurgical units are being examined as well.

The VA Center for Engineering and Occupational Safety summarized the results of the agency's review of its ventilator inventory and five years of work orders for 1,895 ventilators from nine manufacturers, which represent 76% of the current inventory, according to Crisler of the VA. The average number of work orders between August 2013 and August 2014 was 0.41 per ventilator, or less than half a work order per device. "This reiterates the point that the technology is reliable," she said. She itemized common ventilator service issues and problems as follows:

- Oxygen sensor failure/replacement
- Battery failure/replacement
- Compressor failure
- Keypad/button/knob failure
- Displays/screens locked out
- Broken or leaking valves/connectors
- Limited use errors
- Alarm failure
- Casing defects/damage
- Pressure transducer failure
- Patient breathing circuit problems
- Data communication failures to CIS (clinical information system)/ARK (anesthesia record keeper) Systems or nurse call
- Hazard/recall investigations and corrections
  - More than 590 between August 2013 and August 2014
  - Software upgrade
  - Oxygen sensor
- Lack of standardization
  - Communication protocols
  - Terminology

"We are looking at humans as part of a system. Many of our folks think that they are the sole part of care. They can't be perfect. The environment can't always be controlled. There are a range of users, and a range of tasks to consider."

—Tandi Bagian, Director, Human Factors Engineering Division, VA National Center for Patient Safety

"Use errors are very limited," Crisler said. "End users of this technology are very tech-savvy. Respiratory therapists and pulmonologists know how to use the technology and are not afraid of it."

In addition to standardizing ventilator terminology and communication protocols, Crisler believes now is a good time to standardize ways to put ventilators in standby mode and refine the design of ventilators to increase ease of use and troubleshooting features by tracking keystrokes.

The top three faults with home-use ventilators that Gillespie of Advanced Home Care said he sees are transducer faults, usually found in flexible tubing during leak checks; hardware faults, such as fan rubbing; and patient circuits.

Optimizing the User Interface

Many summit presenters and participants zeroed in on the need for common, though not necessarily identical, ventilator user interfaces that are intuitive to navigate.

"A well-designed user interface for a ventilator is safer and more effective for use," said

"There is a tendency to blame users, and for users to blame themselves for 'human error.' Use error is often not described in sufficient detail when incidents are reported. That makes it difficult to understand what's really happening with a device. We need to delve deeper."

—Ron Kaye, Human Factors Expert, FDA CDRH

1. Equipment failure (135 reports)	
Ventilator shutdown	• Spontaneous ventilator shutdown • Controller board failure • Ventilator shut down and came back on, PCB (printed circuit board) in breath delivery unit failed
Other ventilator problems	• Component malfunction • Compressor failure • Regulator pin broken (missing) • Oxygen source not recognized • Ventilator unable to deliver requested tidal volume • Oxygen sensor failed
2. Ventilator settings (46 reports)	
Ventilator setup problems	• New ventilator, lack of standardization for setup
Incorrect ventilator settings	• Ventilator settings not reset after turning patient • Settings adjusted for therapy, not returned to ordered settings • Ventilator set to 0.36 liters vs. ordered 3.6 liters
3. Support activities (40 reports)	
Space	• Environment interferes with auditory alarm signals • Ventilator not safe for MRI environment • Tubing caught on ceiling lift
Utilities	• ICU oxygen outlet does not support ventilator • Ventilator did not recognize external power source • Substation power failure • Ventilator did not have battery backup UPS (universal power supply) unit
Supplies	• Cuffless tracheostomy tube was in a "cuffed" box • Inline humidifier being used with ventilator mask • Rotating air mattress causes tubing disconnection
4. Transport (37 reports)	
Accidental extubation	• Ventilator caught equipment in operating room hallway, pulled out tube • Extubation while unloading patient and equipment from elevator
Other transportation issues	• Ventilator not turned on after patient return from CT • Transport ventilator lacking humidifier
Vehicle-related issues	• Patient ventilator not compatible with ambulance oxygen source • Oxygen transport tank empty
5. Alarm systems (18 reports)	
Alarm settings	• Ventilator alarms turned off • Alarm settings set incorrectly for patient • Volume of ventilator auditory alarm signals turned down to 10%
Alarm connection	• Ability to turn hallway alarm signals off • Ventilator not connected to system • Alarm wire loose
6. Training (7 reports)	
Unknown ventilator model	• Patient admitted with unfamiliar ventilator type • "MRI compatible" vent not familiar to MRI technicians • Unit not trained on ventilator model • Rental equipment
Other training concerns	• Vent malfunctioned • Caregiver unfamiliar with Ambu bag • Water drained back into ventilator

Table 6. Major categories and examples of ventilator-related use issues. Source: Tandi Bagian. "Understanding Use Issues Relating to Ventilators. Presented at the AAMI/FDA Summit on Ventilator Technology, Sept. 16–17, 2014.

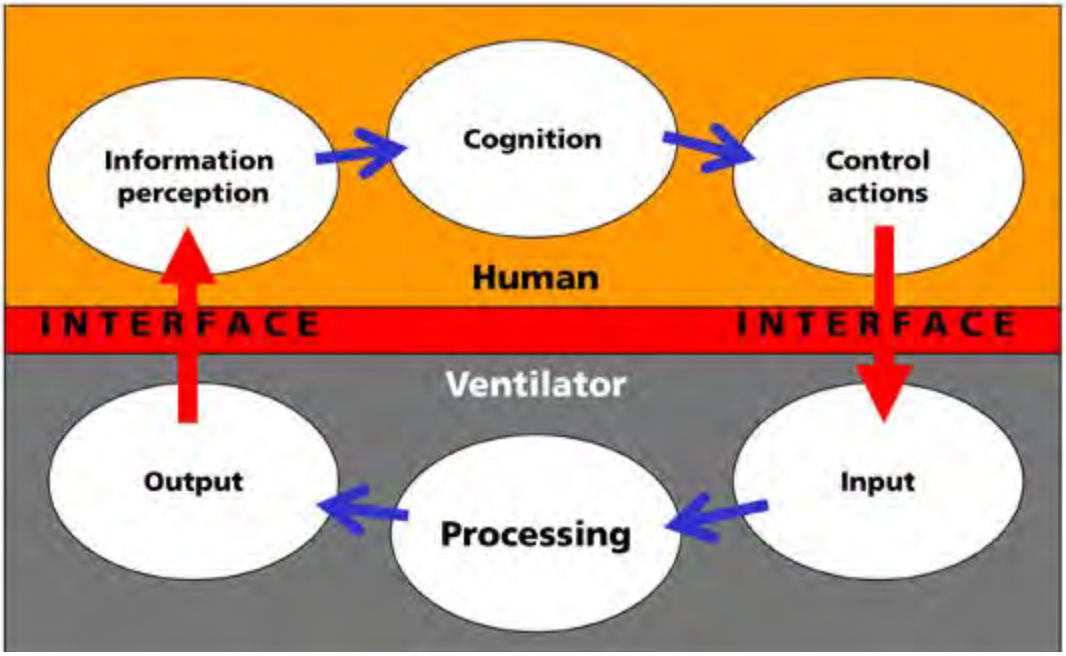


Figure 5. User interface for a ventilator (and many other medical devices). Source: Ron Kaye. "Human Factors Pre-market Review of Ventilators." Presented at the AAMI/FDA Summit on Ventilator Technology, Sept. 16–17, 2014.

summit presenter Ron Kaye, a human factors expert at FDA CDRH. "Poor design of the user interface will cause use error—such as incorrect therapy, delayed treatment, or lack of treatment—that could be prevented by good design." Notably, the device user interface includes the design of the controls and displays, labeling, and user documentation and training, he said. Figure 5 shows a model of the interface and interactions between the human and the ventilator adapted from the FDA's 2011 draft guidance, *Applying Human Factors and Usability Engineering to Optimize Medical Device Design*.

Because ventilators are safety-critical devices, human factors data and review are high priorities for FDA premarket review, Kaye said. "We are aware at the agency of use problems," he said, "usually cases where the device operates fine when you test it on the bench, but when you test it in the use environment, with users, something goes wrong."

Premarket human factors reviews focus on task analysis, risk analysis and prioritization of user tasks according to the impact of potential use error for each task, and evaluation of the use environment for elements that can impede users' ability to perform critical tasks, such as stress, workload, lighting, and distractions, with these specific FDA considerations:

- **Use error considerations** that describe use errors in sufficient detail when incidents are reported and how identified use errors are addressed in design modifications within the context of use (e.g., user expectations, sequence of user interactions, intentions, and interpretation of what resulted [or could result] from user actions).
- **Human factors testing** to detect user interface problems and useful data about testing, including:
  - **Simulated use performance data** focused on challenging the user interface design with representative users, uses, and use environments, with a high priority given to critical tasks performed within naturalist use scenarios
  - **Data collected for each critical user task:** pass, fail, "close call," "operational difficulty"
  - **Subjective assessment data.** Because

National and International Standards and Guidance

Human factors engineering is a component of risk management that had been in place in other industries, such as aviation and power, but was largely unknown in the medical device industry until relatively recently, according to Kaye of the FDA.

Over the past 15 years or so, national and international standards have heightened awareness about human factors design and engineering for medical devices. Relevant standards include:

- ISO 80601-1-2-12:2011 *Medical electrical equipment – Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators*
  - "Primary operating functions" support identification of critical user tasks for human factors testing
- IEC 60601-1-6:2010 *Medical electrical equipment – Part 1-6 General requirements for basic safety and essential performance – Collateral standard: Usability*
- IEC 62366:2007 *Medical devices – Application of usability engineering to medical devices*. A revised version of this standard (IEC 62366-1) will be released in spring 2015.
- ANSI/AAMI HE75, 2009/(R)2013 *Human factors engineering – Design of medical devices*

Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management, a 2000 FDA guidance document:

- Introduced use error as a kind of risk largely distinct from risk associated with the reliability of device operation.
- Introduced "use-related hazard."
- Described medical device "use safety" as resulting from the "device + user system" and the "use environment."
- Described the application of human factors engineering as a component of risk management.

When final, a 2011 FDA draft guidance document, *Applying Human Factors and Usability Engineering to Optimize Medical Device Design*, will supersede the 2000 guidance.

testing simulations might not capture all failures, human factors evaluations should include systematic subjective assessment from test participants following simulated use, with open-ended questions to elicit responses about the use of the device overall, critical tasks, and task failures, close calls, and use difficulties.

Connecting Usability, Risk Management, and Software Validation

Summit presenter Bill Somerville, system engineer section leader, ResMed Ltd., shared his company's approach to delivering quality by applying usability and risk management standards.

ISO 62366:2007 – *Application of usability engineering to medical devices* defines a pathway for using ISO 14971:2010 – *Application of risk management to medical devices* and IEC 62366:2007 – *Application of usability engineering to medical devices*. Figure 6 shows how ResMed applies these standards to improve ventilator quality throughout the design, development, and risk management processes.

Early testing of new concepts improves usability. For example, engineering, marketing, and clinical teams at ResMed thought an innovative new component to improve the disassembly, cleaning, and reassembly of a ventilator component was great, Somerville said. Clinicians and home caregivers loved the idea as well—but disassembly and reassembly were too difficult, so the company scrapped the concept.

ResMed also tested a mockup of a user interface and workflows for main ventilator functions designed well in advance of the software. Common difficulties were exposed and explored with users, and workflows were modified before user interface coding. "We realized significant savings to the project timeline than if this was left to usability testing on the prototype device," Somerville said.

ResMed also carefully controls, traces, and tests changes in ventilator software with a three-tiered approach: specifying system, subsystem, and software requirements and then developing the software code. That means that each block of code effectively is

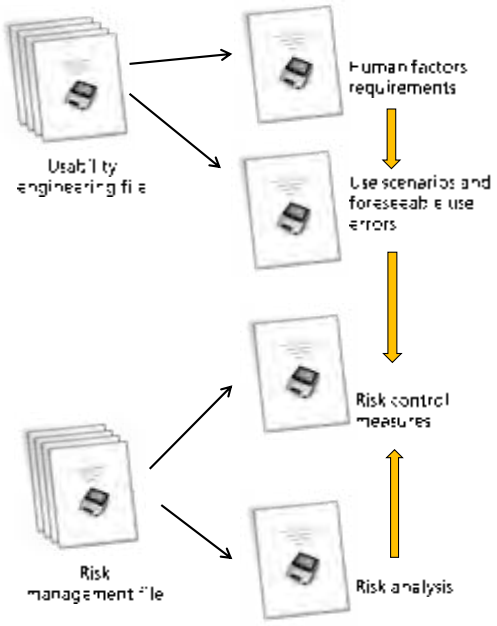


Figure 6. Risk management and usability. Source: Bill Somerville. "Device Quality—Usability, Risk Management, and Software Validation. Presented at the AAMI/FDA Summit on Ventilator Technology, Sept. 16–17, 2014.

tested three times, to validate that it meets the requirements at each tier. "Requirements arising from risk control measures are always retested on release candidates," Somerville said. Regression analysis and static analysis further ensure device quality.

The ventilator industry could learn from other industries with products with a high software content how to methodically validate medical device software, according to the FDA's Richard Chapman, branch chief of the General Hospital Devices Branch in the Office of Device Evaluation at CDRH. "Basically, you make a product safe and effective by reasoning about your product and software," he said. "You have to reason about the software and the product and actually think about what your product is doing and how it meets human needs. The software industry knows how to make high-quality software, using very stringent analysis," including model-based development and testing, formal methods and mathematical proofs, MC/DC automated testing, and rigorous requirements analysis, along with static analysis.

"When you do those first three, you have to think very carefully about what the model is," Chapman said. "You're really checking the software twice, once when you do the math, and second when you do the coding. MC/DC testing, which is the stalwart of the aviation industry, requires going through each line of code and testing the conditional statement. A lot of people just fix errors, but they don't take the time to analyze errors."

"You have to reason about the software and the product and actually think about what your product is doing and how it meets human needs. I urge you to look at how other industries validate their software."

—Richard Chapman, Branch Chief, General Hospital Devices Branch in the Office of Device Evaluation, FDA CDRH

The Power of Simulation For Evaluating Ventilators

Simulation is a powerful tool to evaluate medical device safety and usability, according to summit presenter Stuart McGrane, MB, ChB, assistant professor of clinical anesthesiology, anesthesiologist and critical care physician, Vanderbilt University Medical Center. "Simulation is a situation or environment created to allow persons to experience a representation of a real event for the purpose of practice, learning, evaluation, testing, or to gain an understanding of system and human factors," he said.

"Simulation needs to happen. Academic medical centers will welcome manufacturers. This relationship building needs to start happening."

—Stuart McGrane, Assistant Professor of Clinical Anesthesiology, Anesthesiologist, and Critical Care Physician, Vanderbilt University Medical Center

Putting ventilators to the test in a simulated ICU environment can expose safety risks in rugged settings. ICUs treat very sick, fragile, high-risk patients in crowded, stressful, noisy environments, McGrane noted. Multiple life-support technologies with poor interconnectivity are common. Multidisciplinary teams of physicians, respiratory therapists, and nurses who typically have not trained together are responsible for patient care.

Simulations are beneficial because they put actual users through the paces of using medical devices in a realistic work environment, with a full range of clinical situations—at no risk to patients, McGrane said. The same situation, including rare

Managing Risk with Safety Assurance Cases

Historically, manufacturers assert that their systems are safe with this argument: "I have safety requirements, I followed a development standard, I did some testing (here are my tests)," said Arnab Ray, a senior research scientist at the Fraunhofer USA Center for Experimental Software Engineering and associate adjunct professor with the Department of Computer Science, University of Maryland College Park.

"What's wrong with this picture?" Ray asked. He listed severe gaps in safety arguments:

- What is the context of your system?
- How did you come up with the safety requirements?
- How much can we trust your processes and documentation?
- How do your verification results establish the safety requirements?

Safety assurance cases are an emerging approach for companies to make convincing assertions about hazard analysis and life-critical device safety. What is a safety assurance case? The FDA's Chapman explained:

- A safety assurance case is structured *argument*, supported by a body of *evidence*, which provides a compelling, comprehensive, and valid case that the system is safe for a given application in a given environment.
  - The structured argument (rationale) demonstrates that the evidence it contains is sufficient to show that the system is safe.
  - The argument is commensurate with the potential risk and the system's complexity.

"A safety case is nothing more than safety engineering," Chapman said. Figure 7 shows an example of how a safety assurance case can be organized.

"Is this yet another thing I have to do?" Ray asked, anticipating potential reluctance to develop safety assurance cases. "If you follow proper safety engineering system and software practices, you already have a safety assurance case. If you are building a system, let the safety assurance case drive your development."

Ray advised companies to distinguish the safety argument, which establishes the goal, from the confidence argument, which establishes faith in the evidence. Evidence must be relevant, exhaustive, and trustworthy.

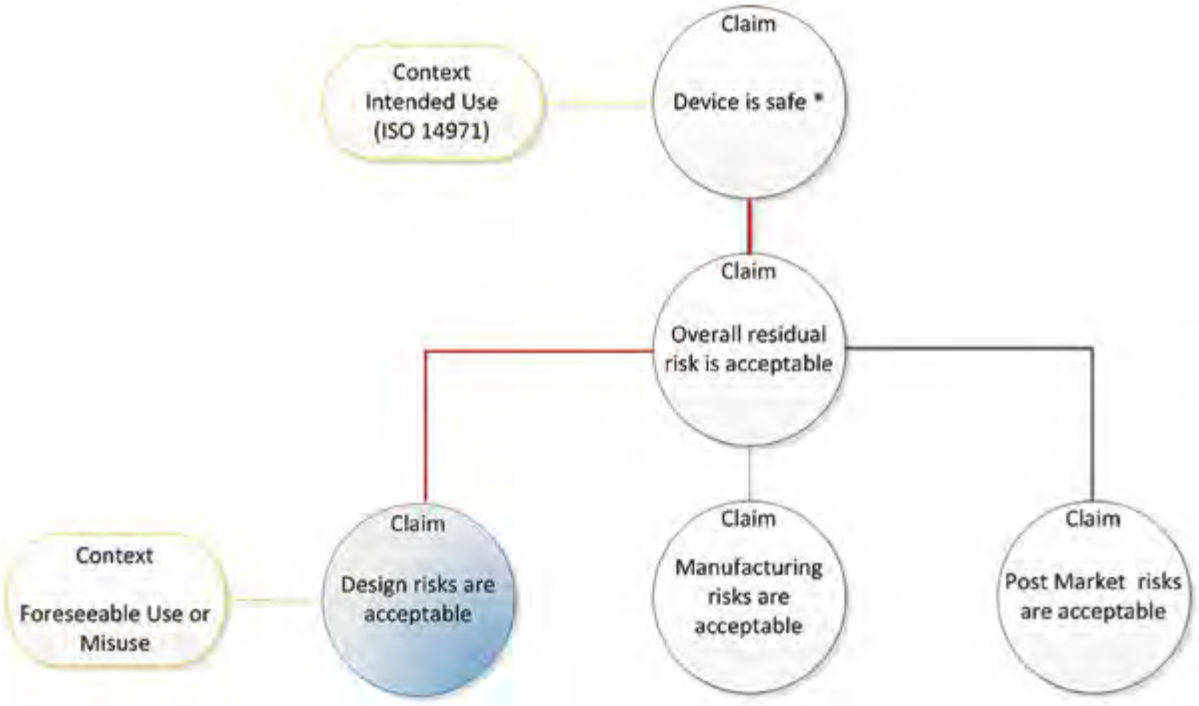


Figure 7. Organization of a sample safety assurance case. Source: Richard Chapman. "Quality System Challenges (Software Validation, Risk). Presented at the AAMI/FDA Summit on Ventilator Technology, Sept. 16–17, 2014.

events, can be repeated many times. Controlled evaluation and creations of error-producing conditions can provide an estimate of use error incidence not otherwise available in the literature.

Simulation can be used at every stage of medical device development, design, evaluation, and postdeployment review, as shown in Figure 8.

Simulation can be designed with varying levels of fidelity and complexity, depending on the device and test goals. McGrane recommended this approach to simulation for testing:

- Define objectives
- Identify tasks, users, and use environment(s)
- Create simulation scenarios to meet the objectives
- Choose appropriate outcomes and how they will be measured
- Create a full simulation test plan

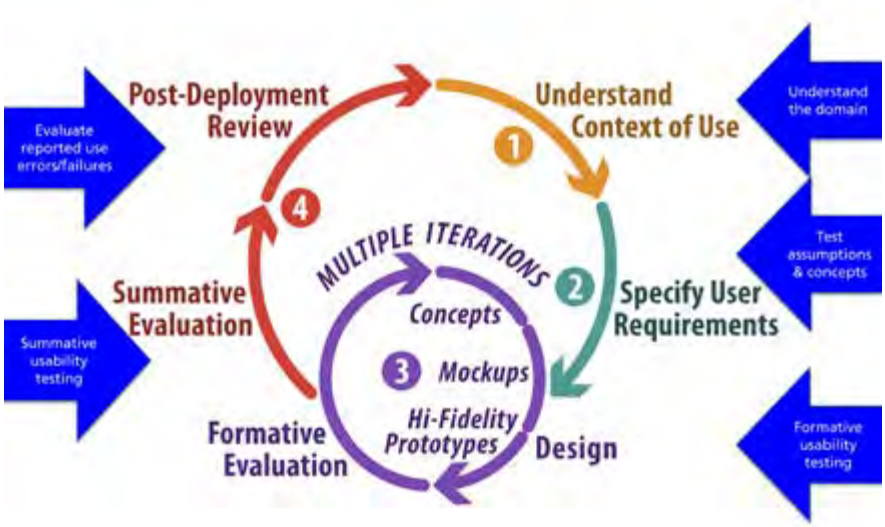


Figure 8. When should simulation be used? Source: Stuart McGrane. "Simulation and Usability Testing." Presented at the AAMI/FDA Summit on Ventilator Technology, Sept. 16–17, 2014. Adapted from ANSI/AAMI/IEC 62366:2007. Image courtesy of Vanderbilt University.

McGrane offered this concluding advice to industry: "Don't try this at home." Simulation requires experts to design and run high-fidelity simulation evaluations. Only some user experience and human factors professionals have this expertise. "The cost of building your own facility is significant," he said. "It is best to reach out to academic medical center facilities that do simulation-based device evaluations."

Rapid Feedback For the Ventilator Industry

At times, it seems as though there is a huge chasm between medical device manufacturers and clinical users. ResMed Corporation has partnered with the University of California San Diego Medical Center (UCSD) Respiratory Care Department to try to bridge that divide and refresh its organizational knowledge.

According to Michael Madison, senior portfolio manager with the Respiratory Care Business Unit at ResMed Corporation, the partnership provides opportunities for the firm's engineering, marketing, purchasing, customer service, and finance staff to:

- See a hospital from the staff's side.
- Learn basic respiratory care terminology.
- Understand how a respiratory therapy department works.
- Understand how respiratory therapists interact with ventilators.

These opportunities include visits by ResMed employees to UCSD and learning programs at the company presented by clinical experts and key opinion leaders at UCSD and other academic medical centers.

ResMed also has a respiratory care advisory board that includes representatives from teaching, community, and long-term acute care hospitals, subacute facilities, and home healthcare providers. These advisors provide a pathway for rapid feedback on ventilators in development and a network for recruiting focus group participants and usability testing participants. "A lot of times we spend a lot of money to identify user needs," Madison said. "We use the advisory board as a sounding board to get rapid feedback and do rapid prototyping, and understand quickly how things can go wrong."

"There's a human on the end of everything we do."
—Michael Madison, Senior Portfolio Manager, ResMed Corporation, and President, California Society for Respiratory Care

Calls for Physiologic Closed-loop Ventilation

Four summit presenters advocated for greater use of physiologic closed-loop ventilation to enhance the safety and effectiveness of ventilator technology.

Essentially, physiologic closed-loop ventilation is an automated, adaptive system that

controls and adjusts ventilation based on the physiological responses of the patient. "Closed loop systems are often described as intelligent systems because they compare the set control variable to the measured control variable" (Pilbeam & Cairo, 2006).

"Pressure support is a simple example of closed-loop control," said summit presenter Rich Branson, a professor of surgery at the University of Cincinnati. "Flow is manipulated to maintain a preselected pressure." There are different types of closed-loop ventilation. Branson listed the current state of the art as follows:

- Mandatory minute volume (MMV)
- Adaptive pressure control (e.g., PRVC, APV, Volume control +, AutoFlow)
- Adaptive support ventilation (ASV)
- AutoMode
- Proportional assist (PAV)
- Neurally adjusted ventilatory assist (NAVA)
- SmartCarePS

"In our working group, we believe there is an unmet need this closed-loop technology can address. We want to be proactive and learn from other industries, such as the airlines, device simulation, and control system analysis."

—Bahram Parvinian, Leader, Closed-loop Medical Devices Working Group, FDA

Branson and Hargett of The Methodist Hospital (Houston) listed these benefits of physiologic closed-loop ventilation:

- Enhanced safety
- Reduced variation in practice
- Provision of a standard of care regardless of the environment and caregiver skill
- Response to changes in patient condition that cannot be accomplished given staffing ratios and severity of illness
- Increased speed of response
- Escalated therapy when required
- Facilitation of ventilator discontinuation
- Decreased length of stay on ventilators
- Increased time at optimal ventilation
- Reduced caregiver interactions
- Decreased alarm condition activations
- Less sensitivity to internal wear and tear of the system

Reducing the amount of time that clinicians need to spend managing ventilated patients is a decided benefit at a time when there is a growing number of mechanically ventilated patients and projected workforce shortfalls of internists and pulmonologists to care for them, Hargett said.

Houston Methodist has adopted physiologic closed-loop ventilation for 33% of its patients, which works out to 20 to 25 patients per day. Just because it's automated, however, doesn't mean that it's simple. Physicians, respiratory therapists, and nurses go through three years of training and take an annual course that includes simulation, case studies, and animal models.

Clinicians do need to understand the autonomous (clinical) decision-making history of the ventilator and the clinical status of their patients, because they may be called in to intervene if a malfunction occurs or patient status changes.

Nelson Claure, MSc, PhD, of the University of Miami School of Medicine made the case for physiologic closed-loop ventilation as an alternative clinical tool for the care of premature infants. "Whatever happens to those babies has strong repercussions in their lives, their families' lives, and society," said Claure, who is an associate professor of pediatrics and director of the Neonatal Pulmonary Research Laboratory, Division of Neonatology, Department of Pediatrics.

Neonatal ventilation is a delicate balance between adequate oxygenation and toxicity from insufficient or excessive oxygen, either of which poses severe risks, Claure said. Yet a study of 14 neonatal ICUs (Hagadorn et al., 2006) found that babies spend only about half of their time on ventilators within the intended range of oxygen saturation (SpO_2). Factors affecting the maintenance of SpO_2 include:

- Respiratory instability of the preterm infant, which increases with postnatal age and with evolving chronic lung disease
- Inadequate manual adjustment of the ventilator, which contributes to insufficient weaning and delayed response
- Staff limitations (education and awareness, workload)

Fully dedicated nurses at bedside can make dozens of adjustments to standard ventilators to maintain ideal ranges of fraction of

inspired oxygen (FIO_2) in premature infants—an indication of the labor intensity of mechanical ventilation for this patient population. Automated ventilators close this loop, as shown in Figure 9, and do a better job of keeping these patients within prescribed target ranges.

Moving forward, Branson identified these challenges to greater penetration of closed-loop ventilation in the market:

- Understanding the regulatory pathway
- Understanding the market demand
- Understanding the cost/benefit
- Evidence to suggest which physiologic closed-loop controls have advantages
- The best environments in which to deploy this technology

The FDA's James Lee, CDRH engineering team leader, presented regulatory considerations for the use of physiologic closed-loop control systems. He cautioned that the risks of oscillation and overshooting of target ranges by these systems could offset the benefits. These risks could reduce safety by:

- Making the system unstable due to uncontrolled gain
- Requiring higher scrutiny of minor design changes
- Increasing the potential for harm if the feedback loop breaks
- Resulting in open-loop conditions
- Introducing new hazards

Lee shared these regulatory considerations for developing physiologic closed-loop ventilators:

- Scientifically validate models of a device and physiological systems.
- Consider human factors early in development.
- Consider alarm fatigue.
- Conduct quantitative analysis before clinical studies to document the internal workings of the device.

Lee also noted:

- Clinical assessments of potential hazards inform engineers of the analytic questions that need to be addressed.
- Rigorous control systems analysis may reduce the size of or eliminate the need for some clinical studies.

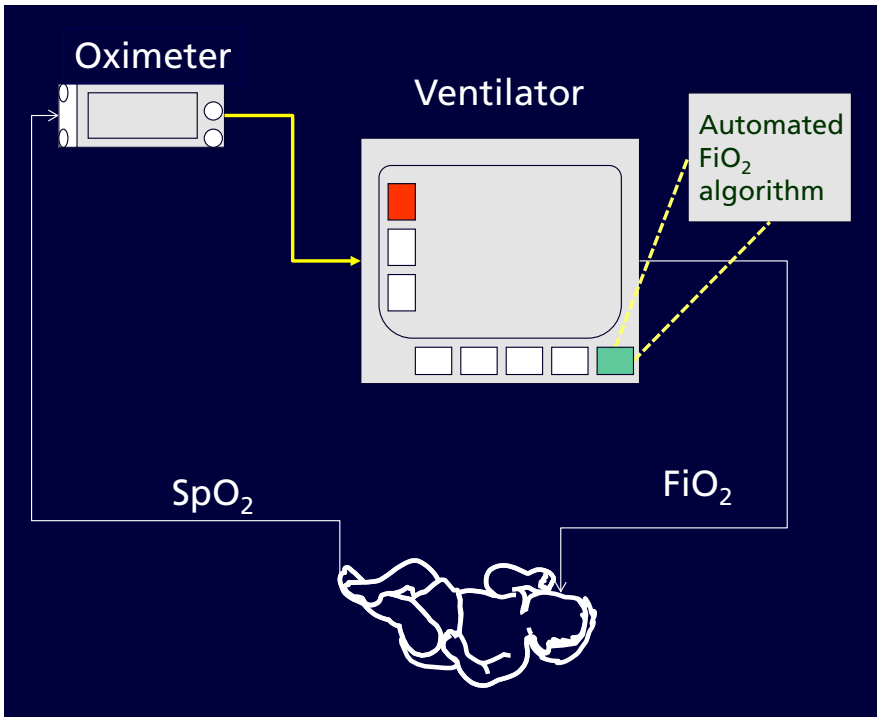


Figure 9. Closing the loop. Source: Nelson Claure. "Physiological Closed-Loop Systems: Closed-Loop Control of Inspired Oxygen for the Premature Newborn." Presented at the AAMI/FDA Summit on Ventilator Technology, Sept. 16–17, 2014.

- Minor changes in the device design may have profound effects on performance.
- Complex systems may need to be simulated if exact solutions are impractical.
- Simulations may not fully represent a population.

CLARION THEME 6

Embrace strong and transparent cooperation, coordination, and collaboration among all stakeholders.

"As a clinician with little experience in the regulatory/manufacturing world, the summit was truly eye-opening for me. It was wonderful to get to interact with and learn from professionals with perspectives outside of the bedside clinician role."

—Matthew Trojanowski
Manager, Adult Respiratory Care Services
The Johns Hopkins Hospital

Challenge	Priority Action	Accountable*
Strong need for more cooperation, coordination, and collaboration among regulatory bodies to improve ventilator technology	Advocate for strong and transparent cooperation, coordination, and collaboration to create a more transparent regulatory playing field.	**FDA** **IMDRF** Other regulatory bodies
Inadequate communication and collaboration about ventilator technology among industry, clinical organizations, and clinicians	Create stronger, more open ways for manufacturers and clinicians to communicate more regularly, with feedback loops beyond a single event. Make reporting of ventilator issues and problems easier and more readily available to all users. Develop communication pathways between industry and clinicians to support continuous learning.	**ASA** **AARC** **HTSI** Patient safety organizations ECRI Institute

*Key organizations indicated by boldface type.

Time and again, summit participants circled back to the need to create a culture of safety, both to address the challenges of ventilator technology and as an aspirational goal for healthcare. The only way to achieve that culture of safety is with strong and transparent cooperation, coordination, and collaboration among all stakeholders.

The FDA is on board with that. In a keynote presentation, William H. Maisel, deputy director for science and chief scientist at CDRH, and acting director of the Office of Device Evaluation, said the center's vision statement is "all about the patients":

- **Patients in the United States have access** to high-quality, safe, and effective medical devices of public health importance **first in the world.**
- The **United States is the world's leader in regulatory science, medical device innova-**

tion and manufacturing, and radiation-emitting product safety.
- U.S. **postmarket surveillance quickly identifies poorly performing devices,** accurately characterizes real-world performance, and facilitates device approval or clearance.
- Devices are legally marketed in the United States and remain **safe, effective, and of high-quality.**
- **Consumers, patients, their caregivers, and providers have access** to understandable science-based information about medical devices and use this **information to make healthcare decisions.**

The FDA is key, but not the only player, in getting cutting-edge medical technology to patients quickly. The FDA focuses on evidence, but access to advanced medical devices also requires market innovation and competition, shorter time for reimbursement from payers, and value.

"We're living in a global economy," Maisel said. "Healthcare delivery has changed. There's a drive to get patients out of hospitals and into the home. That creates new challenges—issues with reliability, differences between hospitals and homes, new scientific and regulatory challenges for us."

CDRH's 2014–15 strategic priority is to strike the right balance between premarket and postmarket data collection. With ventilator technology, that encompasses biocompatibility, usability testing, physiologic closed-loop systems, alarm systems, software validation, and risk mitigation strategies. "The issues raised with ventilator technology are cross-cutting issues—areas where we struggle across device areas," Maisel said. "We will leverage the information from this summit to other device areas."

CDRH also is stepping up its efforts to collaborate with industry, professional societies, academia, and national and international standards-developing organizations (SDOs). "Stakeholder engagement is the attitude we've tried to take in developing policies and making decisions," Maisel said. "We want feedback." For example, CDRH reaches out to networks of experts around the world, including manufacturers and clinicians on the front lines of care, to get quick feedback on pressing issues. And the center is working with SDOs and regulators internationally to harmonize standards and make the device review process more consistent for manufacturers that market products globally.

In addition, CDRH launched the Medical Device Innovation Consortium (MDIC), the first-ever public–private partnership created with the sole objective of advancing medical device regulatory science. Consortium members include the Centers for Medicare & Medicaid Services and the National Institutes of Health, professional societies, manufacturers, foundations, healthcare systems, and patient-centered organizations. MDIC has three priorities:

1. Patient-centered benefit–risk assessments
2. Computational modeling and simulation
3. Clinical trial and innovation reform

In April 2013, CDRH released *Strengthening our National System for Medical Device Postmarket Surveillance,* a report that communicates a vision for streamlining postmarket activities. Now, the center is working with the Brookings Institute's Engleberg Center for Health Care Reform and multiple stakeholders on strategies to achieve that vision; the first part of this plan is expected in 2015, Maisel said.

"This summit is emblematic of our goal of working with the healthcare community. We need a global approach to tackle problems that affect the global ecosystem."

—William H. Maisel, Deputy Director for Science and Chief Scientist, FDA CDRH

CDRH also is working to link and leverage the use of registries to strike the right balance in premarket and postmarket regulation. The registries will provide information and data to multiple stakeholders, which will promote common understanding and streamline the regulatory process.

Finally, the FDA collaborated with the Office of the National Coordinator for Health Information Technology (ONC) and the Federal Communications Commission (FCC) to examine the revolution in digital health and new issues with device security, cybersecurity, interoperability, and big data. Their *2014 FDASIA Health IT Report,* released in

April 2014, proposes a strategy and recommendations for a risk-based framework.

Reaching Out to Industry for Critical-to-Quality Inspections

The three pillars of the FDA's Case for Quality initiative, launched in 2011, are device quality, increased data transparency, and stakeholder engagement. The FDA conducted a listening tour with industry to define what matters to quality, how to achieve quality, and whether quality system regulations are adequate for postmarket inspections, said the FDA's Francisco Vincenty, acting branch chief, Respiratory, ENT, General Hospital, and Ophthalmic Device Branch, Division of Manufacturing and Quality, Office of Compliance.

"What is the common understanding of the risks?" Vincenty asked. "How do you close risks? What is baseline risk, what is above? How do we incentivize risk management and take quality to a higher level?"

The Critical-to-Quality concept focuses more on quality, not just compliance, and on transparency. The new concept is at an early stage, not yet in effect, said Lt. Viky Verna, senior regulatory officer with CDRH.

"We want to learn about controls and successful practices from industry," Verna said. "The Critical-to-Quality information inspections will add more value and focus to the QSIT [quality system inspection technique] inspection," which will continue to be the method for conducting inspections.

"The purpose of Critical-to-Quality information for inspections is to guide FDA investigators in examining how well firms are controlling ventilator features and characteristics that can most likely impact the device's safety and effectiveness," Verna said. The FDA has identified these preliminary risk areas internally, based on common flaws seen in inspections and other internal data sources:

- Power support
- Failure to cycle
- Essential functions
- Alarm systems
- Software
- Accessories/components
- Biocompatibility
- Gas quality

Now, CDRH is reaching out to industry subject matter experts to discuss these risk areas and develop quality information for inspection, with a method for making that information public. "Both the investigator and industry will know what the inspection will focus on," Verna said.

Hungry for Information

For virtually every deficiency identified with ventilator technology, summit participants repeatedly cited a lack of information and communication as barriers to solving problems. The summit proved to be forum for sharing some of that information.

Medical device recalls are on the rise in general, and ventilators are no exception. Summit presenter Ann Ferriter, director, Division of Analysis and Program Operations, Office of Compliance, CDRH, shared data on ventilator recalls.

"Class I ventilator recalls have increased markedly since 2012, when we developed 11 new recall policies. Ventilator recalls was one of those policies. We found we had underestimated the risk, or not thought seriously enough about ventilator-dependent patients. This was a change internally in the FDA recall process—the devices are not getting worse." Radiological, cardiovascular, chemistry, general surgery, general hospital, and orthopedic devices had the most recalls.

Figure 10 shows the causes of ventilator recalls. Figure 11 shows the number of Class I, II, and III ventilator recalls. Components and software are particular focus issues for the FDA, Ferriter said. "We do a couple of thousand surveillance inspections a year. We have put ventilators on a risk-based work plan."

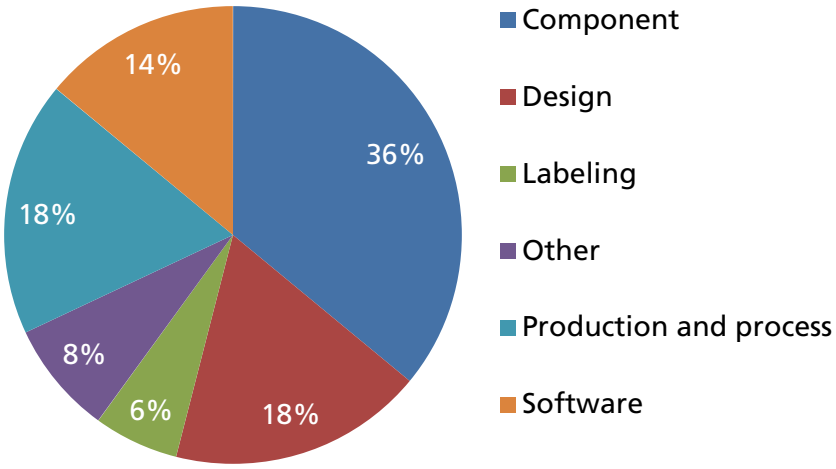
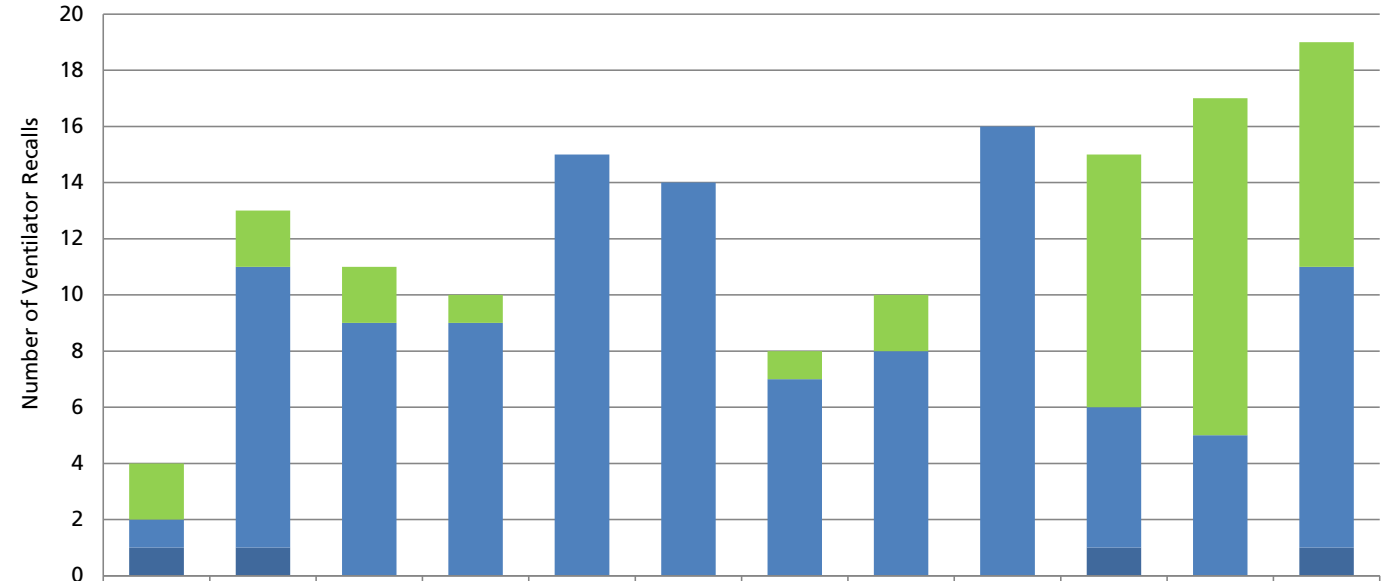


Figure 10. Causes of ventilator recalls. Source: Ann Ferriter. "FDA Medical Device Data." Presented at the AAMI/FDA Summit on Ventilator Technology, Sept. 16–17, 2014.



	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Class I	2	2	2	1			1	2		9	12	8
Class II	1	10	9	9	15	14	7	8	16	5	5	10
Class III	1	1								1		1

Figure 11. Ventilator recalls, 2003–2014. Source: Ann Ferriter. "FDA Medical Device Data." Presented at the AAMI/FDA Summit on Ventilator Technology, Sept. 16–17, 2014.

CREATE A CULTURE AND AN INFRASTRUCTURE FOR COMMUNICATING AND SHARING KNOWLEDGE

Summit participants cited inadequate information and communication from users to industry, and vice versa, about use errors and device malfunctions. They brainstormed these potential solutions:

For Clinicians and Healthcare Delivery Organizations

- Document use errors and device malfunctions immediately.
- Treat every event, not just adverse events, as patient safety risks and report all events. (Near misses aren't always reported.)

For Manufacturers

- Provide websites and phone lines for users to log in or call in to submit information.
- Strengthen follow-up on user feedback by investigating errors to make sure they don't happen again.
- Build on training partnerships with users by sharing common use issues and encouraging users to report both adverse and minor events and other use issues.

For Regulators and Advocates

- Improve the usability of the FDA's MAUDE database and encourage its use.
- Build forums for non-FDA disclosed, easy communication of minor events.
- Develop training on how to report use issues consistently and with sufficient specificity and detail to identify root cause(s)—with a recommendation that AAMI and manufacturers take ownership of this activity.

Conclusion

Participants and presenters at the AAMI/FDA Summit on Ventilator Technology shaped a vision of a safer and more effective environment of care for patients who depend on ventilators—remarkable, life-saving equipment that could be even better. When this vision becomes a reality, ventilated patients and the entire healthcare community would benefit from:

- Clear, standardized language for mechanical ventilation and ventilation modes, used broadly and consistently to improve patient care and enhance clinical information.
- Shared understanding of biocompatibility expectations for ventilator technology—and a safer, clearer, faster path to market.
- Clinicians who are consistently trained, competent, and certified to care for ventilated patients and operate the ventilators they use.
- Integrated devices and systems, including alarm systems, that provide clinicians with comprehensive, actionable information about ventilated patients.
- Intuitive and consistent user interfaces that make it easy to set up and operate ventilators in clinical and nonclinical settings.
- A strong and transparent culture of cooperation, coordination, and collaboration in which shared information spurs improvements in the safety and outcomes of mechanical ventilation.

This vision is eminently achievable. New and revised standards on ventilation-related terminology and biocompatibility are in the works and should be available soon. Guidance, best practices, recommendations, and innovations point the way to solutions for education and training, device and systems integration, and thoughtfully designed user interfaces.

A culture of safety is what's needed, in which all stakeholders—from executives to front-line providers—are working toward improved patient outcomes and see a culture of safety as the ultimate goal of healthcare.

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RELEVANT STANDARDS AND GUIDANCE

Work Environments

- AACN Standards for Establishing and Sustaining Healthy Work Environments

Terminology

- ISO 19223, *Lung ventilators and related equipment — Vocabulary and semantics* (in development)

Biocompatibility

- FDA Blue Book Memorandum G95-1, *Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices*
- ANSI/AAMI/ISO 10993-1:2009/(R)2013, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process and ISO 10993 Parts 2–18* (a few of which are still in development)
- *Use of International Standard ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing": Draft Guidance for Industry and Food and Drug Administration Staff* (April 23, 2013) (public comments under evaluation)
- ISO/CD 18562, *Biocompatibility evaluation of respiratory gas pathways in healthcare applications* (series, in development)
- ISO 17510-2:2007, Sleep apnoea breathing therapy – Part 2: Masks and application accessories

Medical Device and System Integration

- ANSI/AAMI/IEC 80001-1:2010, *Application of risk management for IT networks incorporating medical devices – Part 1: Roles, responsibilities and activities*
- ANSI/AAMI/IEC TIR 80001-2-1:2012, *Application of risk management for IT-networks incorporating medical devices—Part 2-1: Step by step risk management of medical IT-networks; Practical application and examples*
- ANSI/AAMI/IEC TIR 80001-2-2:2012, *Application of risk management for IT-networks incorporating medical devices—Part 2-2: Guidance for the communication of medical device security needs, risks and controls*
- ANSI/AAMI/IEC TIR 80001-2-3:2012, *Application of risk management for IT-networks, incorporating medical devices—Part 2-3: Guidance for wireless networks*
- ANSI/AAMI/IEC TIR 80001-2-4:2012, *Application of risk management for IT-networks incorporating medical devices—Part 2-4: Application guidance—General implementation guidance for healthcare delivery organizations*
- IEC/TR 80001-2-5, *Application of risk management for IT-networks incorporating medical devices: Application guidance—guidance for distributed alarms* (in development)

Human Factors Engineering

- IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices* (Revision due in 2015)
- ANSI/AAMI HE75: 2009/(R)2013, *Human factors engineering – Design of medical devices*
- IEC 60601-1-6:2010, *Medical electrical equipment – Part 1-6 General requirements for basic safety and essential performance - Collateral standard: Usability*
- *Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management: Guidance for Industry and FDA Premarket and Design Control Reviewers* (July 18, 2000)
- *Draft Guidance for Industry and Food and Drug Administration Staff – Applying Human Factors and Usability Engineering to Optimize Medical Device Design* (June 22, 2011)

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Society of Critical Care Medicine

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