



Four Case Studies of Biomedes Who Went Above and Beyond

An RCA Team's Rapid Response....346

In Houston, Communication Was Key During Flood Recovery....348

A Near-Miss with a Tubing Connection....351

Routine Checks Reveal Cause of Equipment Failures....353

Improving Patient Safety: More Than Repairs for Today's Biomedes

Jill S. Williams

Biomedical equipment technicians and clinical engineers have always been on the front lines of patient safety in hospitals. From the electrical safety scares of the early 1970s to today's focus on reducing medical errors, medical equipment professionals are called on to ensure that medical technologies in the healthcare environment are safe to use.

Here, *BI&T* presents four stories of equipment professionals who went above and beyond to guarantee patient safety in their hospitals. One story springs from a disaster response; two focus on adverse event investigations; and one began with device damage noticed during routine preventive maintenance checks. In each story, equipment professionals brought their unique combination of engineering and clinical skills to the task.

Our four experts also share their opinions about what the role of clinical engineers and biomedical equipment technicians should be in today's patient safety-centered healthcare environment. Medical equipment professionals must play a major role in patient safety, they say. Key advice:

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- Speak up and be available to participate in your hospital's patient safety program, including technology assessment teams and incident investigation teams.
- Learn about the risk management process, including incident investigations, root cause analysis, and failure mode and effects analysis.
- Use medical equipment databases to identify trends that affect patient safety.
- Become a member or subscribe to organizations that offer the information needed to stay current with patient safety.
- Branch out into nonequipment areas.
- Strengthen partnerships with clinical staff and leverage relationships to improve patient safety.
- Take advantage of any opportunities to become involved in patient safety.
- Work with manufacturers to improve device safety.

As Bryanne Patail of the VA's National Center for Patient Safety says, "If your department's mission statement says that it is your job to ensure the cost-effective, safe application of medical devices, then just repairing equipment is not enough."

RCA Team Determines Causes of Inadequate Sterilization

When an OR nurse at a large teaching hospital noticed that the stripes on a surgical pack's ethylene oxide (ETO) indicator tape were still brown, she became concerned. The brown stripes change to red if properly sterilized. This pack's brown stripes indicated that it had not been properly sterilized, and presented a major problem for the operating room. A quick investigation found that surgical packs used on five previous OR cases that day were also not sterile. The surgery was stopped, and the incident was reported to the hospital's administration, OR chief, legal affairs department and the director of clinical engineering.

Bryanne Patail, now with the Department of Veterans Affairs National Center for Patient Safety, was the director of clinical engineering at that hospital at the time the incident occurred. He played a key role in its investigation. At a recent AAMI Annual Conference session, he used this incident to illustrate the use of root cause analysis (RCA) in an investigation and to highlight the role that clinical engineers and biomedical equipment technicians can play in such investigations.

First, Patail and his colleagues sequestered all surgical packs processed the previous day by the ETO machine and chartered a multidisciplinary RCA team. "A root cause analysis aims to answer three questions: What happened? Why did it happen? And what can we do to prevent it from happening again?" says Patail.

The RCA team conducted interviews to better understand the incident. They found that ETO packs processed the day before were the only ones affected. The ETO machine had been repaired the day before by an in-house BMET. Upon investigation, the Central Sterile Processing (CSP) supervisor noticed that the machine was programmed to cycle faster than normal. The clinical engineering director reviewed the work order and interviewed the BMET who serviced the ETO machine, who acknowledged that part of his routine was to cycle the ETO machine faster. On this occasion, he had forgotten to reset the machine to normal operation. As a result of this faster cycle, the surgical packs were not exposed to ETO for the required amount of time, and thus their sterility could not be ensured.

The team also looked at the procedural failures that allowed the questionable surgical packs to make it into the operating room. They found several contributing

factors: verification of sterility was not part of the OR checklist; the OR staff was rushing because they were behind schedule; three OR staff had called in sick; those who were working had worked a double shift the previous day. "With pressure to meet OR schedules and bonuses based on volume, the financial culture trumped the safety culture," says Patail.

Once the machine was reset to normal parameters, its proper operation was verified by both the BMET and the CSP supervisor. The five patients who underwent surgery before the sterilization problem was caught were notified of the event and offered free testing for infections; 30-day follow-up of these patients showed no problems as a result of the incident.

To prevent future incidents, Patail, the RCA team, and the clinical engineering department developed a new post-sterilization repair testing and verification procedure. Under the new procedure, technicians were no longer permitted to change the ETO settings to cycle the machine faster for testing. A checklist was added to verify that machine settings were at the hospital's standard protocol at the conclusion of testing. In addition, the CSP supervisor had to verify proper machine operation and sign off on the work order after testing.

"We had to disallow the fast cycle to prevent the same mistake from happening again," says Patail. "It's not a perfect solution, because now testing will result in 2 hours of ETO exposure on a full cycle rather than 15 minutes on a fast cycle." It was, however, the best solution that could be obtained under the circumstances.

While some may consider this response to be overkill, Patail argues that it is necessary to avoid a single point failure. "Although the service person has been 'directed' not to cycle the device, there is a chance that during the calibration and testing of the different functions of the machine, the clock could be reset to the wrong setting. Therefore, the checklist and the SPD supervisor checking in tandem will catch 99% of the vulnerabilities. The directive not to cycle will ensure 100%. With these safeguards, the culture of safety trumps the culture of cost/profits."

Fixes resulting from root cause analyses can range from strong to weak, Patail says. The strongest changes are those most likely to eliminate or greatly reduce the likelihood of an event; they typically use physical plant

or system fixes with the application of human factors principles. In this case, the best solution would involve the manufacturer redesigning the equipment to be more maintenance-friendly, providing a test cycle that automatically reverts to the standard cycle after testing.

Intermediate actions likely to control the root cause or vulnerability employ human factors principles, but also rely upon individual action, such as a checklist or cognitive aid. Thus, a checklist was added and a second review—the CSP supervisor's signature on the work order—provided confirmation. The weakest actions are those that rely on policies, procedures, and training

(individual action) in isolation of other fixes.

“To my knowledge, the manufacturer has not yet changed the design of the machine,” says Patail. “Their usual answer is ‘perhaps at the next model change.’ I would like CEs and BMETs to join me in fighting for these kinds of changes. Rather than always looking internally to make changes, hospitals should consider trying to force changes at the device design level,” he says. CEs and BMETs, accustomed to working with manufacturers, filing device incident reports, and evaluating new equipment purchases, are uniquely positioned to spearhead these efforts. ■

Capture Opportunities to Be Patient Safety Experts

As a biomedical engineer with the Department of Veterans Affairs National Center for Patient Safety based in Ann Arbor, MI, Bryanne Patail, MS, MLS, FACCE, is heavily committed to advancing the cause of patient safety at the VA's 154 hospitals across the nation. And, as a clinical engineer with more than 30 years of experience in the field, he is also committed to seeing clinical engineers and biomedical equipment technicians use their unique skills and training to become patient safety experts.

“Clinical engineers and biomedical equipment technicians are excellent candidates to share their knowledge and apply systems engineering and other tools to build a better healthcare delivery system,” says Patail. “CEs and BMETs can use their expertise in systems analysis and troubleshooting and their knowledge of equipment to change the culture of safety in healthcare.” An excellent way to do this, he says, is to participate in multidisciplinary teams, such as technology assessment teams and root cause analysis or failure mode and effect analysis teams.

How do CEs or BMETs who don't already play a role in their hospital's safety culture break into that area? “Speak up, and be available at the table,” advises Patail. “Take advantage of opportunities. Back in the '90s, the user reporting requirements of the Safe Medical Devices Act offered a chance for equipment professionals to get involved with safety; now, the Institute of Medicine report on patient safety and other patient safety initiatives present new opportunities.”

He points out that the reporting chain is important. If you're part of an in-house department, you need a direct reporting line to medical administration. “Patient safety is a medical issue, there should be a reporting line somewhere,” he says. “If not, seek out a medical administrator in charge of quality assurance and work directly with them.”

If you're part of an outsourced department, he says, look at the language of your contract. “If your work is strictly repair, there is no avenue to get involved in safety. However, if you are providing total equipment services, then safety is part of your domain.”

Patail also advises equipment professionals to branch out into nonequipment areas. “Don't limit yourself to just medical devices,” he says. “Get involved with patient falls, IT systems, medication mistakes, IT interoperability standards, design of new hospital facilities. All of these areas involve patient safety and can benefit from the expertise a CE or BMET could bring to the table.”

What training do CEs and BMETs need to take on such a role? “They need to understand the whole risk management process, take courses in root cause analysis and failure mode and effect analysis, and be prepared to be part of a team,” says Patail. The VA's National Center for Patient Safety is an excellent source for classes on safety-related issues; see www.patientsafety.gov.



Bryanne Patail

Texas Biomed Team Steps Up During Natural Disaster

In June 2001, Tropical Storm Allison devastated the Houston Metro area and surrounding communities. Five days of pounding storms dropped up to 37 inches of rain in the area, and Houston was hit with what was then the worst urban flood in U.S. history. The flood closed down Memorial Hermann & Children's Memorial Hermann hospital in the Texas Medical Center for the first time in its history, leading to a massive effort to evacuate patients and protect medical equipment.

Douglas Dreps, biomedical engineering manager with Memorial Hermann's clinical engineering department, lives 60 miles from Houston and was on his way out of town when he got the news about the flood.

"The funny thing was that I had my bags packed and was ready to attend the AAMI convention when my wife called me over to the TV, because she saw that the hospital was flooded," says Dreps. "When I saw a grand piano floating in the water, I knew that my trip was cancelled and I needed to try to get to the hospital as soon as possible. The piano that was floating on the television was one floor above the clinical engineering department. I knew that the clinical laboratories, cath labs, and other departments were also submerged."

During the early hours of the morning, the hospital lost all power when vital electrical components were submerged under water. A decision was made by the CEO to evacuate all patients. Over the next 36 hours, nearly 300 volunteers carried and assisted 540 patients down darkened stairwells and halls to ambulances and Life Flight, Black Hawk, and Coast Guard helicopters. They used flashlights and other portable lights to find their way in the dimly lit hospital. Patients were transferred to several hospitals around and outside the city. And, because those hospitals needed extra equipment to care for those patients, Memorial Hermann's equipment went with them.

When Dreps arrived on the scene early that afternoon, about 22 feet of water stood between the basement and the ground floor of the main hospital building. Four other buildings were also flooded. With many of his staff trapped by the flooding and unable to get to the hospital,



Biomedical equipment technicians helped to evacuate both patients and equipment in the aftermath of Tropical Storm Allison.

Dreps and his team leader, Robert Koehl, were the only medical equipment staff on hand for the first 24 hours of the emergency. Gradually, his full team of 15 was on the job along with imaging and electronic technicians from clinical engineering.

He found his entire clinical engineering department under water. All test and repair equipment in the department was a total loss, along with any other medical equipment there awaiting repair. Fortunately, the medical equipment database was stored on the hospital's IT backbone and the data were safe. The entire clinical laboratory and five cardiac cath labs housed in the hospital's basement were also destroyed.

The hospital administrative team was working out of a command center set up in the emergency room. "It all revolved around patient safety," says Dreps. Dreps and his team brought their skills as engineers and medical equipment specialists to meet the changing needs of the situation. First, their focus was on helping facility engineering set up temporary generators to provide power to the buildings, and hanging temporary lighting. Next, they helped evacuate patients. Finally, and for the next

several weeks, Dreps and his team focused on equipment needs.

“The key in the beginning was to get the equipment to where the patients were going,” he says. “We had to hand-carry ventilators and other patient care equipment down nine flights of dimly lit stairs.” A typical ventilator and its cart can weigh well over 100 pounds.

Keeping track of where equipment was going was a major challenge. “Initially, in the panic of that first 36 hours, the equipment was just going out the door with the patients and nobody was keeping track of it,” Dreps says. Fortunately, all of the equipment was already labeled with the hospital name and a barcode that hooked into the hospital’s equipment database, and much of the equipment went to sister hospitals that used

the same equipment database.

“Then, we started putting tags on all of the equipment with my name and phone number on it. We kept a paper spreadsheet of where all the equipment was going, and put it all on a computer as soon as one became available.”

Saving the equipment remaining in the building was the next focus. All equipment stored in flooded areas was a total loss. Other equipment was also in danger from exposure to water, heat, and humidity. “There were 42 million gallons of water sitting in the building, and it took several days to pump it all out,” says Dreps. “Any equipment under water was discarded, anything in an area filled with water was questionable.” To protect imaging equipment and other valuable medical devices,

Information, Networking, Communication Key to Patient Safety Role

Douglas Dreps believes that the medical equipment database was key to his department’s ability to manage and recover from the 2001 flood that shut down his hospital for six weeks. He also thinks it is key to his department’s ongoing contribution to patient safety in the hospital.

“If you instill in your technicians that they need to document everything properly, you can use these powerful databases to identify trends that affect patient safety,” he says. “We can tell when and where equipment was bought, what was spent on it, what use errors occur with it.”

Clinical engineers and biomedical equipment technicians are patient safety advocates, says Dreps, and need to make nursing, administrators, and IT better understand the importance of that role. “Saying we have value is not good enough. We need to be more aggressive with our presence at nursing, administration, and IT meetings and strategic planning committees.”

Rapidly evolving medical equipment had also changed that role. “Maintenance of equipment was once the main way we affected patient safety,” says Dreps. “As equipment has become more reliable, we can now focus on evaluating and implementing new patient safety technologies.” He points to technology

that integrates medical devices into electronic medical records as one that will improve patient safety through reduction in translation errors.

Dreps’ technicians take an active role in addressing use errors, educating staff on proper use of equipment, and working with department heads and educators to address use error trends.

His department also holds regular medical equipment subcommittee meetings where nursing, risk management, education, materials management, and administrators are invited to address the medical equipment Environment of Care portion of JCAHO requirements.

Keeping up with new technologies and meeting with others in the engineering and affiliated fields are also key to improving patient safety, Dreps says. “Engineering and IT leadership now meet weekly at my institution to improve our relationship and work together on technologies that improve patient safety,” he says.



Douglas Dreps, biomedical engineering manager with Memorial Hermann's clinical engineering department.



“Having our equipment database on the IT backbone was key. Even though our whole department was under water, we didn’t lose any data.”

Dreps and his team set up air conditioning units and fans to dry and cool the equipment as soon as temporary power became available, within 48 hours of the initial power loss.

As the flood waters subsided and the hospital began the cleanup process, all equipment had to be cleaned, inspected, and recertified. “Our focus became moving the equipment back in, getting it back in place, and getting ready to reopen.”

The hospital reopened six weeks later, on July 17, with limited services. It did not return to full operation for another two months. From the flood to the reopening, Dreps and his staff worked 18-hour days, providing 24-hour-a-day coverage, seven days a week to handle equipment needs.

What have Dreps and his team learned from this disaster? “First, you can’t always prepare for a disaster, because you don’t know what the disaster will be,” he says. “Having our equipment database on the IT backbone was key. Even though our whole department was under water, we didn’t lose any data.”

Now, Dreps has key people assigned to track equipment leaving the building in case of another such emergency. The disaster plan also calls for twice daily conference calls with hospital leadership to discuss clinical engineering issues.

At Memorial Hermann Healthcare System, they have learned to take hurricane preparedness seriously. Before Hurricane Rita hit in September 2005, the system closed

two hospitals and evacuated all patients beforehand. Biomed staff moved key equipment away from windows, and helped maintenance board up the windows. While Rita wound up not causing much damage in Houston, an affiliated hospital in Beaumont did suffer water damage. Some of Dreps’ staff spent several weeks there helping them recertify equipment. ■

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Coming up in the next issue of
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- ✓ Preparing for a Deposition: What Biomedics Need to Know
- ✓ Career Center: Making the Transition from Engineer to Manager
- ✓ EQ56: Recommended Practice for a Medical Equipment Management Program
- ✓ CAPA in the Modern Quality System
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“Near Miss” Prompts Hospital-Wide Effort to Eliminate Tubing Misconnects

In late 2005, while visiting a patient in the hospital, a family member noticed a disconnected hose lying on the bed near the patient. Not wanting to bother the nursing staff, the family member connected the tube to a needleless input port on a catheter line. Minutes later, a nurse arrived in the room and noticed blood in the input port tubing. She traced the tubing and saw that the noninvasive blood pressure (NIBP) cuff inflation hose was attached to the port. She immediately disconnected the hose and reattached it to the NIBP cuff, informing the family members not to connect or place any lines or cables on the patient but to instead contact the nursing staff.

The NIBP module was three minutes away from activating an automatic blood pressure determination. If that would have happened, the patient would have been infused with close to 1.5 liters of compressed air in one

minute. Instead, the rapid response of the nurse saved the patient's life and gave the hospital a chance to learn from the incident and prevent it from happening again.

The nurse contacted risk management and filled out an unusual occurrence report (UOR) as required by clinical policy. An emergency intensive assessment task force was assembled following this adverse event that included representatives from nursing, biomedical engineering, risk management, pharmacy, and senior medical and clinical executive staff members.

Dave Stiles, director of biomedical engineering at Long Beach Memorial Medical Center in Long Beach, CA, was part of this team. “We determined that the connection system used on the NIBP inflation systems consisted of male and female luer-style slip fittings that can result in the misconnection to a compatible port not intended for the blood pressure hose,” says Stiles. “It was

	Collect	<h3>Managing your environment of care just got easier . . .</h3> <ul style="list-style-type: none"> easily report and track incidents and issues + increase quantity and quality of incident data collected + distribute and track hazards, alerts and recalls + always know status of opened/closed issues + deliver immediate alerts + escalate open items + improve response time + document actions taken + quickly generate executive, regulatory and hospital performance reports + analyze data to track and provide valuable information on safety trends by location, EOC domain, incident type and other factors <p>Too good to believe? Not with St. Croix Systems real-time, Web-based Safety Manager solution. Call or e-mail today for your online demonstration: 781.272.7900 or sales@stcroixsystems.com.</p> <p>st·croixsystems www.stcroixsystems.com</p> <p style="text-align: right;"><i>Better Equipped to Care™</i></p>
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Safety Manager		

acknowledged at that time that ECRI, AAMI, and the FDA had also reported similar adverse events.”

As a result of the incident and its investigation, the medical center decided to replace all the luer-style connectors on all of its blood pressure devices. “Biomedical contacted several vendors and selected a bayonet-style quick disconnect connection system,” says Stiles. Within seven days of the incident, the biomedical engineering team tested, procured, and installed a new connection system on every blood pressure machine and sphygmomanometer in the medical center.

“We worked with the manufacturer of the disposable cuffs to convert from the slip luer to the bayonet style cuff connector prior to the conversion,” says Stiles. “It turned out that they anticipated this change and were prepared to help us in the conversion. We purchased the hose connector from an independent manufacturer specializing in pneumatic fittings to complete setup.”

On the day of the swap-out, Biomedical worked with Materials and systematically swept the complete medical center, converting the NIBP connection system to the bayonet style, says Stiles. He estimates that they converted close to 1,600 cuffs and hoses during an eight-hour shift.

Such a rapid change presented unique challenges for clinician education. Stiles’ team broadcast, via e-mail and fliers, a quick in-service on how to connect and disconnect the tube and cuff. “We provided on-site in-servicing to clinicians not familiar with this connection system,” he says. The medical center also included a video discussion of the incident as an example of its patient safety program during its annual clinical skills lab and safety fair.

Since this incident, Stiles and his team have identified several potential areas of misconnection including sequential pressure devices, respiratory gas and patient safety lines and tubing, and enteral feeding pumps. “We did not see any problems with medical gas systems or fittings, as we were following NCG and NFPA standards in regards to medical gas delivery devices,” he says. He reports that his team’s main focus was avoiding attaching non-IV products to IV sets or catheters with female luer slip fittings attached. They also ensured that all disposable respiratory breathing circuits and other circuits did not include removable luer fittings that could be removed and attached elsewhere.

“We have tested our devices for misconnections and have worked with the manufacturers to correct this

patient safety issue,” he says. “All of the medical device manufacturers we contacted concerning misconnects cooperated with our medical center in establishing a work-around to avoid medical misconnections.”

“The greatest lesson learned in this experience,” says Stiles, “is that we did not heed the early published warnings of tubing misconnects and were complacent in adopting these changes.” ■

Incident Leads to Stronger Role for Biomed in Patient Safety

As a result of this incident, Memorial Medical Center’s biomedical department has taken a stronger role on the patient safety committee, informing members of adverse events and product problems that could result in unexpected adverse patient events. Involvement in safety committees is essential to clinical engineers and biomedical equipment technicians becoming “stewards of patient safety,” says Dave Stiles.



Dave Stiles

Another key to playing this role is to become a member or subscribe to organizations that offer the information needed to stay current with patient safety. “Don’t limit yourself just to clinical engineering groups, visit the medical side as well,” says Stiles. “Get invited to the many nursing conferences that involve patient safety.”

Consistently sharing all your findings with the nursing staff can help you communicate to clinicians that you, too, are part of the frontline defense when it comes to ensuring patient safety. “Get into the habit of distributing alerts and equipment issues involving patient safety with the nursing staff, not just by e-mail, but by in-services, safety fairs, and one-on-one encounters,” he says. “You have to get to know your two most important partners in your field: the patients and the clinicians.”

Problems with Device Cleaning Uncovered by Preventive Maintenance Checks

Preventive maintenance tasks are at the heart of most medical equipment management programs, but no one much likes them. For technicians they can be tedious, and for clinicians they can be an interruption. Yet, in this case, routine preventive maintenance inspections uncovered a dangerous situation that affects whole categories of devices.

Wallace Elliott is a clinical engineer with Fletcher Allen Healthcare, a 450-bed hospital in Vermont. He and his staff of seven BMETs routinely inspect the hospital's 520 Sigma 8000 infusion pumps. In recent inspections, technicians noticed degradation of plastics in the chassis of the pumps. The chassis is the plastic housing that covers the device, protecting its internal components from fluid spills. Technicians were seeing most of the damage in crevices where fluid could pool, particularly where the infusion set is inserted into the device. In some of the components, cracks were causing chipping of the plastic. These cracks could allow fluids to enter the device, causing failures.

"Pump failures were experienced due to this problem," says Elliott. "As a result, we inspected all 520 pumps. We found that the protective housing on approximately 200 pumps was compromised and had to be replaced at a cost of \$75 to \$185 per unit."

Fortunately, the team's annual testing identified the problem before devices failed during clinical operation. "For us, the most significant consequence of the issue has been the financial impact of repairs," says Elliott.

The infusion pumps were only two years old, and had an expected lifespan of seven years. Elliott suspected that the hospitals' cleaning fluid was causing the cracks, because it pooled on the devices exactly where the cracks were appearing. Pumps are cleaned between every patient. The cleaning protocol requires that the pumps be adequately covered with an antiseptic solution, which must be left on the device for a period of time in order to achieve the "kill factor" of the antiseptic solution.

"The manufacturer asked us what cleaning fluid we were using," says Elliott. "It turns out that there is a very long list of cleaning fluids that Sigma does not want you to use, and a very short list of acceptable fluids."



Technician T.C. Bugbee performs functional tests on infusion pumps at Fletcher Allen Health Care in Burlington, VT.

The manufacturer was very helpful in tracking down the problem, Elliott says. "They did extensive testing with fluids we sent them to try to identify the problem."

Elliott and his team began inspecting other devices for damage to plastic housings. They found problems with syringe pumps and infant abduction identification bracelets that had to be replaced. Similar problems with surgical lamps were avoided because they were notified in time by the manufacturer of incompatibility between ingredients in a certain disinfectant spray and the Lexan polycarbonate resin used to make the lights. Problems have also been identified with circumcision boards and glucometers, and his team is currently checking pulse oximeters.

The hospital convened a committee of representatives from different departments including housekeeping, infection control, nursing, and clinical engineering to investigate the problem. "We began looking closely at user manuals and found that each manufacturer has a different list of acceptable fluids to be used to clean their device." They discovered a wide-spectrum problem with device and cleaning fluid compatibility. "Solving this

problem is not easy," says Elliott. "Every manufacturer wants different fluids. There are no one or two commercial fluids that are acceptable for use on all or even most devices."

While most devices permit cleaning using soap and water, the hospital's infection control department requires that devices in many environments be disinfected. It is these commercial disinfectants that created the problems with the plastics. Dilute bleach solutions and alcohol are alternatives to commercial disinfectants, but dilute bleach solutions need to be prepared on a daily basis and can be difficult to use on clinical units, and alcohol causes cracking of certain plastics.

Until the problems can be resolved, Elliott says that the hospital's housekeeping staff is using more bleach and alcohol to clean devices, and doing more centralized cleaning. "They have to be very careful about which fluids to use on which devices," he says. "This is requiring a great investment in training for our staff, and it has created logistical problems with purchasing and storage to have the right fluids available where they are needed."

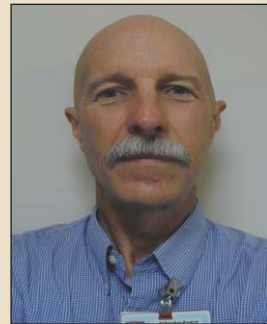
"Manufacturers are aware of this problem, and quick to say that hospitals are not following instructions in the user manual," says Elliott. "That is, if you read the user manual, and most people don't. The manufacturers' sales people certainly don't emphasize this issue during sales calls, and it is not highlighted during training."

Elliott's group has not focused on requiring clinical departments to pay closer attention to instruction manuals, he says. "Many instruction manuals are so long that to be realistic, we do not expect all of the fine print to be read by the clinical departments. Rather, we have attempted to change the acquisition process in such a way as to determine whether equipment has special cleaning requirements prior to purchase," he says.

Elliott and his colleagues have begun discussing this problem with the FDA, which has not yet formed an opinion on the issue. "We would like to see greater standardization in this area," says Elliott. "My hope is that manufacturers will start using plastics that are less susceptible to these types of problems. I would like them to do the design work that would eliminate this problem for us." ■

Equipment Experts Bring Unique Skills to Patient Safety Effort

As Wallace Elliott's story shows, clinical engineers at his facility are very involved in patient safety issues. Formally, a clinical engineering representative sits on the hospital's Environment of Care committee (formerly the safety committee), and chairs the Equipment Management subcommittee.



Wallace Elliott

They are routinely involved in incident investigations where a device may have played a role.

What is Elliott's advice to CEs or BMETs looking to play a bigger role in patient safety? "Find an advocate in the administration or on the clinical side that sees the benefit of having a biomed play a role. Once you have an opportunity, make the benefits of your participation obvious."

BMETs' combination of technological and clinical skills makes them essential members of the safety team, Elliott argues. "Healthcare has become so reliant on technology," he says. "Someone must be sitting at the table who understands the shortcomings of technology and can relate those to potential safety problems. A hospital is missing a key piece of the safety puzzle if they don't include that expertise."

Plus, Elliott says, equipment professionals are uniquely qualified to work with manufacturers to encourage changes in device design to improve equipment safety. Achieving such changes takes knowledge and persistence. "Manufacturers often prefer working with the clinical staff because they can be easier to brush aside," says Elliott. "Clinical engineers stay in the manufacturer's face until something is resolved."