TOP 10

ECRI Institute

2019 Top 10 Health Technology Hazards

Executive Brief

A Report from Health Devices

2019 Top 10 Health Technology Hazards

Executive Brief

ECRI Institute is providing this abridged version of its 2019 Top 10 list of health technology hazards as a free public service to inform healthcare facilities about important safety issues involving the use of medical devices and systems. The full report—including detailed problem descriptions and ECRI Institute's step-by-step recommendations for addressing the hazards—is available to members of ECRI Institute programs through their membership web pages.

The List for 2019

1. Hackers Can Exploit Remote Access to Systems, Disrupting Healthcare Operations
2. "Clean" Mattresses Can Ooze Body Fluids onto Patients
3. Retained Sponges Persist as a Surgical Complication Despite Manual Counts
4. Improperly Set Ventilator Alarms Put Patients at Risk for Hypoxic Brain Injury or Death
5. Mishandling Flexible Endoscopes after Disinfection Can Lead to Patient Infections
6. Confusing Dose Rate with Flow Rate Can Lead to Infusion Pump Medication Errors
7. Improper Customization of Physiologic Monitor Alarm Settings May Result in Missed Alarms
8. Injury Risk from Overhead Patient Lift Systems
9. Cleaning Fluid Seeping into Electrical Components Can Lead to Equipment Damage and Fires
10. Flawed Battery Charging Systems and Practices Can Affect Device Operation

The Purpose of the List

The safe use of health technology—from simple devices to complex information systems—requires identifying possible sources of danger or difficulty with those technologies and taking steps to minimize the likelihood that adverse events will occur. This list will help healthcare facilities do that.

Produced each year by ECRI Institute's Health Devices Group, the Top 10 Health Technology Hazards list identifies the potential sources of danger that we believe warrant the greatest attention for the coming year. The list does not enumerate the most frequently reported problems or the ones associated with the most severe consequences—although we do consider such information in our analysis. Rather, the list reflects our judgment about which risks should receive priority now.

All the items on our list represent problems that can be avoided or risks that can be minimized through the careful management of technologies. With the additional content provided in the full report, the list serves as a tool that healthcare facilities can use to efficiently and effectively manage the risks.

How Topics Are Selected

This list focuses on what we call generic hazards—problems that result from the risks inherent to the use of certain types or combinations of medical technologies. It does not discuss risks or problems that pertain to specific models or suppliers.

ECRI Institute engineers, scientists, clinicians, and other patient safety analysts nominate topics for consideration based on their own expertise and insight gained through:

- Investigating incidents
- Testing medical devices
- Observing operations and assessing hospital practices
- Reviewing the literature
- Speaking with clinicians, clinical engineers, technology managers, purchasing staff, health systems administrators, and device suppliers

Staff also consider the thousands of health-technology-related problem reports that we receive through our Problem Reporting Network and through data that participating facilities share with our patient safety organization, ECRI Institute PSO.

After the topic nomination phase, professionals from ECRI Institute's many program areas, as well as external advisors, review these topics and select their top 10. We use this feedback to produce the final list, weighing factors such as the following:

- **Severity.** What is the likelihood that the hazard could cause serious injury or death?
- **Frequency.** How likely is the hazard? Does it occur often?
- **Breadth.** If the hazard occurs, are the consequences likely to spread to affect a great number of people, either within one facility or across many facilities?
- **Insidiousness.** Is the problem difficult to recognize? Could the problem lead to a cascade of downstream errors before it is identified or corrected?
- **Profile.** Is the hazard likely to receive significant publicity? Has it been reported in the media, and is an affected hospital likely to receive negative attention? Has the hazard become a focus of regulatory bodies or accrediting agencies?
- **Preventability.** Can actions be taken now to prevent the problem or at least minimize the risks? Would raising awareness of the hazard help reduce future occurrences?

All the topics we select for the list must, to some degree, be preventable. But any one of the other criteria can, on its own, warrant including a topic on the list. We encourage readers to examine these same factors when judging the criticality of these and other hazards at their own facilities.

Not all hazards on the list will apply at all healthcare facilities. Also note that the exclusion of a topic that was included on a previous year's list should not be interpreted to mean that the topic no longer deserves attention. Most of these hazards persist, and hospitals should continue working toward minimizing them. Rather, our experts determined that the topics listed here should receive greater attention in 2019.

1

Hackers Can Exploit Remote Access to Systems, Disrupting Healthcare Operations

Cybersecurity attacks that infiltrate a network by exploiting remote access functionality on connected devices and systems—or by any other means—remain a significant threat to healthcare operations. Attacks can render devices or systems inoperative, degrade their performance, or expose or compromise the data they hold, all of which can severely hinder the delivery of patient care and put patients at risk.

Remote access systems are a common target because they are, by nature, publicly accessible. Intended to meet legitimate business needs, such as allowing off-site clinicians to access clinical data or vendors to troubleshoot systems installed at the facility, remote access systems can be exploited for illegitimate purposes.

Attackers take advantage of unmaintained and vulnerable remote access systems to infiltrate an organization's network. Once they gain access—whether through medical or nonmedical assets—attackers can move to other connected devices or systems, installing ransomware or other malware, stealing data or rendering it unusable, or hijacking computing resources for other purposes, such as to generate cryptocurrency.

Safeguarding assets requires identifying, protecting, and monitoring all remote access points, as well as adhering to recommended cybersecurity practices, such as instituting a strong password policy, maintaining and patching systems, and logging system access.

2

“Clean” Mattresses Can Ooze Body Fluids onto Patients

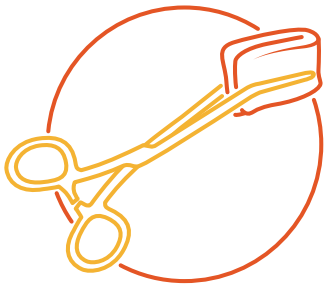
Blood and other body fluids that remain on, or within, mattresses or mattress covers after cleaning can contact subsequent patients, posing an infection risk. Reported incidents include patients lying on an apparently clean bed or stretcher when blood from a previous patient oozed out of the surface onto the patient.

Mattress covers are intended to prevent body fluids and other contaminants from getting into mattresses. If a cover is not cleaned and disinfected effectively, or if its integrity is compromised in a way that allows the mattress underneath to become contaminated, subsequent patients could be exposed to infectious materials. (Mattresses themselves are not cleaned and disinfected between patients.)

Healthcare facilities must take care to use appropriate products and procedures for cleaning and disinfecting mattress covers, and they should regularly inspect mattresses and covers for signs of damage or contamination.

One key challenge, however, is that not all mattress cover suppliers recommend products and procedures that will successfully remove the likely surface contaminants without compromising the cover’s integrity (i.e., creating weak spots that could allow leaks). This situation needs to be remedied.

3



Retained Sponges Persist as a Surgical Complication Despite Manual Counts

Surgical sponges that are unintentionally left inside the patient after the surgical site is closed can lead to infection and other serious complications, including the need for secondary operations.

Manual counts—in which the surgical team verifies that all sponges are accounted for before concluding the procedure—are standard practice, but they are prone to error. If such errors result in a retained sponge, complications can ensue, with consequences for both the patient and the healthcare facility.

Accurate data on the incidence of retained surgical sponges is hard to come by; for one thing, incidents may not be identified unless (or until) the patient returns with a complaint of pain or discomfort. Nevertheless, we know the problem persists. Available data suggests that every year thousands of U.S. patients could experience a retained surgical item (RSI), with surgical sponges being the most commonly retained item.

Technologies that supplement the manual counting process are available and have been found to be effective when used correctly. ECRI Institute contends that broader adoption of these technologies could further reduce the risk that a surgical sponge will be unintentionally retained during a procedure.

4

Improperly Set Ventilator Alarms Put Patients at Risk for Hypoxic Brain Injury or Death

Mechanically ventilated patients are at risk if user-adjustable ventilator alarms are not tailored to the patient's respiratory parameters. Leaks, disconnections, and other failures associated with a ventilator's consumable components are a fairly common occurrence and can quickly lead to harm if the condition is not identified and rectified promptly.

Ventilators are life-support devices that deliver positive-pressure breaths to patients who require assistance to breathe adequately. These devices rely on consumable components, such as plastic breathing circuits, to help convey respiratory gases between the ventilator and the patient. Loose connections, manufacturing defects, or other problems with these components can prevent adequate ventilation. Within minutes, inadequate ventilation can result in hypoxic brain injury or death.

Properly set alarms can prevent such consequences. Yet ECRI Institute continues to investigate deaths resulting from breathing circuit disconnections during which no alarm activated. In two cases from early 2018, alarms to detect inadequate ventilation, such as the minute-volume and low-pressure alarms, were not set appropriately.

Healthcare facilities need policies on setting user-adjustable ventilator alarms and protocols for verifying that the policies are being followed and that component connections are secure.

5

Mishandling Flexible Endoscopes after Disinfection Can Lead to Patient Infections

Cleaning and disinfecting flexible endoscopes between uses is known to be a challenging process. Failure to precisely follow a robust reprocessing protocol can lead to debilitating or even fatal infections. Less well known is that improper handling and storage practices can recontaminate previously disinfected scopes, heightening the risk of patient infections.

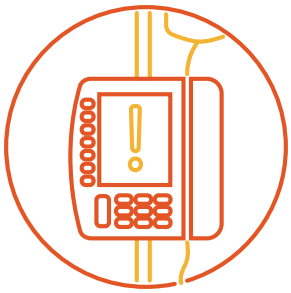
If endoscopes are not completely dried after being subjected to high-level disinfection, any remaining viable microbes can rapidly proliferate and colonize the instruments. To promote drying, ECRI Institute and relevant professional societies recommend purging endoscope channels with clean air at the end of the reprocessing process.

The disinfected status of endoscopes can also be compromised if the instruments are handled with unclean gloves—a practice that ECRI Institute has observed. Endoscopes that have been cleaned but not yet high-level disinfected are still contaminated with viable microbes; thus gloves used to handle an endoscope at that stage must not be used to remove the scope from the reprocessing machine.

Recontamination can also occur when transporting and storing endoscopes. Disinfected and dried endoscopes should be transported in a clean enclosed container, dedicated to that purpose, and should be prevented from contacting potentially unclean surfaces.

6

Confusing Dose Rate with Flow Rate Can Lead to Infusion Pump Medication Errors



Mistakes such as entering the intended flow rate into an infusion pump's dose rate field can lead to dangerous medication administration errors. Clinicians tell us that such wrong-field programming errors occur relatively frequently (though such errors often go unreported). Even "smart pumps" that incorporate a dose error reduction system can be misprogrammed in a way that could lead to patient harm.

Infusion pumps are designed to deliver medications and other solutions to the patient at a specified rate. If the rate programmed into the pump is incorrect, the patient will receive either too much or too little solution. Either situation can have grave consequences, depending on the solution being delivered.

Factors that can contribute to wrong-field programming errors include the layout of an infusion pump's programming screen, the sequence in which infusion programming parameters are listed on the medication administration record (MAR), and the absence of procedures to verify the accuracy of pump programming.

The surest way to eliminate manual-entry errors is to implement autoprogramming of your infusion pumps. Other recommendations include configuring your MAR to match the sequence in which infusion parameters will be entered into the pump and instituting appropriate double-checks to verify pump programming.

7

Improper Customization of Physiologic Monitor Alarm Settings May Result in Missed Alarms

Improper customization of the alarms on a physiologic monitoring system could prevent staff from learning about significant changes in the patient's physiologic status or about problems with the medical device or system. Failure to recognize and respond to such conditions in a timely manner can result in serious patient injury or death.

Physiologic monitoring systems must be designed and configured to strike the proper balance between activating too many alarms (specifically nuisance alarms that can lead to alarm fatigue) and activating too few alarms (which can lead to hazardous conditions being missed). Alarm customization is one practice that can help achieve this balance.

Alarm customization involves selecting alarm values or settings based on the particular needs of a care area and the condition of the patient. When customization is done properly, alarms are less likely to activate for nonactionable conditions, thereby reducing the number of nuisance alarms that activate. But if done improperly, alarm customization can create opportunities for missed alarms, and thus patient harm.

Establishing thoughtful policies and educating staff about optimal alarm-customization practices can help reduce the risks. Additionally, monitoring system vendors offer tools to support customization efforts.

8

Injury Risk from Overhead Patient Lift Systems

Overhead patient lift systems are implemented as a safety technology, but are not without their own safety challenges. Significant injury or damage can occur if the system is designed, installed, used, or maintained improperly.

Overhead patient lift systems are fixed structures designed to lift and transfer patients, such as from a bed to a wheelchair. During use, the patient is placed in a sling suspended from a lifting mechanism. Most overhead lifts use a motorized trolley that travels along an overhead track that is mounted to the ceiling or wall or that is part of a freestanding frame built around a patient bed or other location.

Safety challenges with these systems arise from (1) their installation requirements and (2) their reliance on weight-bearing and moving parts to function dependably, and be used correctly, when lifting and moving a patient. Lift components that fall from above or that fail during use can harm patients, care providers, and visitors.

Risks can be reduced by having qualified personnel install the system, thoroughly testing the system after installation, assessing the condition of the lift before and during each use, and performing regular preventive maintenance.

9

Cleaning Fluid Seeping into Electrical Components Can Lead to Equipment Damage and Fires

Overzealous or improper cleaning of electrical equipment can result in equipment malfunction, damage, or fire. Medical devices and other electrical equipment used in healthcare facilities must be cleaned and disinfected to prevent cross-contamination between patients and curtail the spread of infectious organisms. However, some cleaning practices can present risks.

The use of cleaning or disinfectant wipes that are dripping with excess fluid, or spraying liquids directly onto powered medical devices and equipment, can cause fluid to enter electrical components such as plugs, sockets, or power supplies. Repeated fluid ingress, and the residue it leaves behind, can create errant current pathways around the electrical component. These additional currents can eventually generate sufficient heat to cause a device failure, or worse.

ECRI Institute is aware of multiple instances in which cleaning fluid seeping into electrical components has led to equipment damage or fire. Incidents have involved infusion pumps, OR tables, infant warmers, and electrical equipment such as light switches and power supplies.

When cleaning electrical equipment, staff should follow manufacturer instructions, they should avoid spraying fluids directly onto the equipment, and they should use appropriate cloths, wipes, and sponges (squeezing out excess liquid before use).

10

Flawed Battery Charging Systems and Practices Can Affect Device Operation

Insufficiently charged batteries can affect the readiness and operation of medical devices that rely on rechargeable batteries to temporarily power the device. If no alternative device or source of power is readily available, serious injury or death could result, particularly if the equipment is needed for life-saving or life-sustaining therapy.

Staff failing to properly charge or maintain batteries is one concern. But often the fault lies with the equipment: A device's battery status indicators may not be sufficiently accurate or clear. A battery charger may malfunction. Or the battery itself may be defective or become exhausted.

In one incident, a ventilator's battery-status gauge overstated the charge remaining; the device stopped ventilating the patient shortly after initiating a low-battery alarm. In another, a defibrillator did not clearly warn of a low-battery condition; as a result, the device shut down during a resuscitation attempt.

Adhering to appropriate battery use and maintenance practices is essential. Equally important, but often overlooked, is that assessing battery systems before purchase can go a long way toward ensuring that your facility's devices will operate as expected when running on rechargeable battery power.

ECRI Institute Resources for Addressing the Hazards

Members of certain ECRI Institute programs can access resources such as the following to learn more about the topics included on this year's list:

1. Hackers Exploiting Remote Access Vulnerabilities

Cybersecurity: The Essentials. This web page features a collection of *Health Devices* resources on cybersecurity topics.

Specific articles of interest include the following:

- Cybersecurity risk assessment for medical devices. *Health Devices* 2018 Aug 8.
- Ransomware and other cybersecurity threats to healthcare delivery can endanger patients. Hazard #1—top 10 health technology hazards for 2018. *Health Devices* 2017 Nov 1.

The following related reports were issued through ECRI Institute's *Health Devices Alerts* notification service:

- PACS servers directly accessible from Internet may pose cybersecurity risks [ECRI Exclusive Report]. *Health Devices Alerts* 2018 Jul 25 (Accession No. S0351).
- SamSam ransomware infections may affect care delivery. *Health Devices Alerts* 2018 Apr 25 (Accession No. S0348).

2. Mattresses Remaining Contaminated after Cleaning

Bed and stretcher support surfaces (mattresses and mattress covers): risks of microbiological contamination and fluid ingress [ECRI Exclusive Hazard Report]. *Health Devices Alerts* 2017 Sep 28 (Accession No. H0398).

Damaged or worn bed and stretcher mattress covers may allow fluid ingress. *Health Devices Alerts* 2014 Sep 11 (Accession No. H0237).

Disinfectant concentrations for EPA's list of products effective against *Clostridium difficile*. *Health Devices* 2018 Jun 20.

Disinfectant concentrations for EPA's list of products effective against *Mycobacterium tuberculosis*, human HIV-1, and hepatitis B virus. *Health Devices* 2018 Jun 20.

Mattresses and covers may be infected by body fluids and microbiological contaminants. Hazard #3—top 10 health technology hazards for 2018. *Health Devices* 2017 Nov 1.

Reducing the risks of fluid ingress and microbiological contamination in bed and stretcher support surfaces. *Health Devices* 2017 May 10.

3. Retained Surgical Sponges

Product Evaluations:

- Evaluation background: surgical sponge counting and detection technologies. *Health Devices* 2018 Jun 13.
- Evaluation: Medtronic Situate Detection System X surgical sponge detection technology. *Health Devices* 2018 Jun 13.
- Radio-frequency surgical sponge detection: a new way to lower the odds of leaving sponges (and similar items) in patients [evaluation]. *Health Devices* 2008 Jul;37(7):193-202.
- Stryker SurgiCount Safety-Sponge system surgical sponge counting technology. *Health Devices* 2018 Jun 13.

Guidance Articles:

- Assessing the cost-effectiveness of approaches for reducing retained surgical items—Banner Health's success story. *Health Devices* 2016 Mar 30. Note: The costs used for the calculations outlined in this article have changed significantly in the years since Banner Health conducted its cost analysis, For instance, the proprietary RFID sponges are now priced more competitively. Thus, the same analysis conducted today could lead to a different outcome. Nevertheless, the article illustrates how a cost analysis for implementing an RFID technology could be performed.
- One, two, three, four: I counted all, but found some more. *PSO Compass Point* 2016 May 24.
- Radio-frequency detection facilitates sponge counts. *Health Devices* 2013 Feb 1.

4. Improperly Set Ventilator Alarms

ECRI Institute PSO. Preparing for the unexpected with mechanical ventilators. *PSO Navigator* 2017 Nov 1.

Ventilators: The Essentials. This web page features a collection of *Health Devices* resources on mechanical ventilation. The page provides links to articles describing the function and features of various ventilation technologies, as well as our product Evaluations and guidance on the selection, purchasing, and safe use of these devices.

Ventilator hazards addressed on previous *Health Devices* Top 10 Health Technology Hazards lists:

- Failure to appropriately operate intensive care ventilators can result in preventable ventilator-induced lung injuries. Hazard #9—top 10 health technology hazards for 2016. *Health Devices* 2015 Nov 7.
- Missed ventilator alarms can lead to patient harm. Hazard #3—top 10 health technology hazards for 2017. *Health Devices* 2016 Nov 4.
- Ventilator disconnections not caught because of mis-set or missed alarms. Hazard #5—top 10 health technology hazards for 2015. *Health Devices* 2014 Nov 24.

Following are the *Health Devices Alerts* reports cited in the Background section of the full report (reports are listed in order by Accession Number):

- H0435: *Health Devices Alerts* 2018 Mar 27. This Hazard Report addresses closed suction kits with flex connectors that may become loose or disconnect, potentially leading to inadequate ventilation or staff exposure to biohazardous excretions.
- H0439: *Health Devices Alerts* 2018 Apr 25. This Hazard Report discusses endotracheal tube connectors that were susceptible to becoming detached from the tube, creating the risk for patient harm.

5. Recontamination of Endoscopes after Disinfection

ECRI Institute has included the potential for cross-contamination from reusable medical devices and instruments in several previous editions of our Top 10 Hazards list: See, in particular:

- Endoscope reprocessing failures continue to expose patients to infection risk. Hazard #2—top 10 health technology hazards for 2018. *Health Devices* 2017 Nov 1.
- Inadequate cleaning of flexible endoscopes before disinfection can spread deadly pathogens. Hazard #1—top 10 health technology hazards for 2016. *Health Devices* 2015 Nov 7.

For the complete list, members can refer to "Reprocessing Failures" in the cumulative subject index for the Top 10 Health Technology Hazards.

6. Wrong-Field Infusion Pump Programming Errors

Infusion Pumps: The Essentials. This web page features a collection of *Health Devices* resources on infusion pumps. The page provides links to articles describing the function and features of various infusion technologies, as well as our product Evaluations and guidance on the selection, purchasing, and safe use of these devices.

Specific ECRI Institute articles of interest include the following:

- Dose error reduction systems: features and functions. *Health Devices* 2014 Jun 4.
- Evaluation: BD Alaris Pump module large-volume infusion pump. *Health Devices* 2017 Jan 11. Refer to the discussion of dose entry under the Safety heading in the Significant Findings section of the Evaluation.
- Infusion errors can be deadly if simple safety steps are overlooked. Hazard #1—top 10 health technology hazards for 2017. *Health Devices* 2016 Nov 4.
- Infusion pump integration: why is it needed, and what are the challenges? [guidance article]. *Health Devices* 2013 Jul;42(7):210-21.
- What is infusion pump integration, and which models offer it? *Health Devices* 2018 Jan 17.

7. Improper Customization of Physiologic Monitor Alarms

Collections of ECRI Institute alarm management resources:

- Alarm Management: The Essentials. This page contains our complete collection of guidance, tools, and other resources for improving clinical alarm safety.
- *The Alarm Safety Handbook and Workbook.* ECRI Institute; 2014. These publications offer strategies, tools, and guidance for improving the management of clinical alarm systems.

Evaluation background: ICU physiologic monitoring systems. *Health Devices* Updated 2018 Jul 18.

ECRI Institute web conferences:

- Answering the call to alarm safety: getting ready for Joint Commission's National Patient Safety Goal. 2013 Aug 14.
- Good alarm policies are no accident. 2014 Sep 3.

8. Failures of Overhead Patient Lift Systems

Ceiling-mounted patient lifts: raising the bar for staff safety [evaluation]. *Health Devices* 2009 Apr;38(4):102-13.

Lifts, patient transfer; slings, patient lift. *Healthcare Product Comparison System* 2017 Jan 1.

Patient-handling device use errors and device failures. Hazard #6—top 10 health technology hazards for 2015. *Health Devices* 2014 Nov 24.

Watch your back: how to develop an effective safe-patient-handling program [guidance article]. *Health Devices* 2012 Jan;41(1):6-11.

The following reports related to overhead lift systems were issued through ECRI Institute's *Health Devices Alerts* notification service (January 2015 through August 2018):

- Arjo—Quick Connect scales used with Maxi Sky 2 ceiling lifts: may disconnect from spreader bar. *Health Devices Alerts* 2018 Aug 15 (Accession No. A30225 01).
- Arjohuntleigh— Maxi Sky 600 patient lifts: trolley wheels may be cracked [ECRI Exclusive User Experience Network]. *Health Devices Alerts* 2017 Nov 22 (Accession No. S0336).
- Etac—Molift Rail System traverse switches: manufacturer informs customers of mandatory inspection. *Health Devices Alerts* 2015 May 11 (Accession No. A24240).
- Handicare—coach bolts used to attach ceiling rails to vertical supports: may fracture, potentially causing the rail and vertical support to separate. *Health Devices Alerts* 2017 Feb 17 (Accession No. A27618).
- Handicare—Prism Medical A-625 patient lifts: lift strap may wear prematurely at max load. *Health Devices Alerts* 2017 Oct 26 (Accession No. A29354).
- Hill-Rom—ceiling brackets used with various patient lift rail systems: larger center hole in bracket may lead to system failure in concrete ceiling installations

when safe working load is exceeded. *Health Devices Alerts* 2016 Nov 15 (Accession No. A27506).

- Hill-Rom—Liko Multirall ceiling lift systems: manufacturer reminds users of safe attachment procedures. *Health Devices Alerts* 2017 Nov 30 (Accession No. A29286 01).
- Human Care—Altair and Roomer S overhead lifts: use of 2-point suspension with long distance straps attached between lift unit and rail system may cause unexpected wear of lift belt. *Health Devices Alerts* 2016 Aug 29 (Accession No. A27114).
- Human Care—Altair, HeliQ, and Roomer S overhead lifts: use of emergency lowering button in non-emergency situations may lead to safety problems, patient discomfort, and damage to lift. *Health Devices Alerts* 2016 Aug 29 (Accession No. A27080).
- Medcare—walking slings: may be labeled with incorrect load rating. *Health Devices Alerts* 2015 Nov 12 (Accession No. A25347).
- Moller Vital/Etac—Molift Air patient ceiling hoists: suspension coupling bolt may come loose from housing. *Health Devices Alerts* 2016 Jul 28 (Accession No. A26934).
- Prism—A625 ceiling lifts: straps may break prematurely. *Health Devices Alerts* 2017 Oct 26 (Accession No. A28227 01).
- Prism—C-Series ceiling lifts carry bars: may break if damaged, potentially resulting in patient fall. *Health Devices Alerts* 2016 Dec 16 (Accession No. A27445).
- Prism—C136, CP136, and P136 ceiling lifts: overspeed mechanism may fail. *Health Devices Alerts* 2015 Oct 5 (Accession No. A25133).
- Prism—C300/P300 Series ceiling lifts: drive gear shaft may fail and/or free fall protection system may not engage properly. *Health Devices Alerts* 2016 Feb 1 (Accession No. A25693).
- Prism—Freeway Easy Fit Systems with swiveling trolley: securing pin for mounting hoop may become dislodged. *Health Devices Alerts* 2017 Aug 28 (Accession No. A28869 01).
- Prism—P-440 and P-600 portable celling lifts: sling loops may not remain attached to carry bar hooks. *Health Devices Alerts* 2015 Aug 11 (Accession No. A24801).
- Prism Medical—P-440 and P-600 ceiling lifts: patient injury risk resulting from operator hanging hand control over carry bar hook [Hazard Report]. *Health Devices Alerts* 2015 May 14 (Accession No. H0246).
- Prism—Various Freeway and Mobile hoists: carry bar pin retaining screws may become loose. *Health Devices Alerts* 2015 Apr 16 (Accession No. A24168).

9. Cleaning Fluids Damaging Electrical Components

Cleaner and disinfectant fluid ingress in electrical medical devices and electrical equipment may cause equipment damage and fires [ECRI Exclusive Hazard Report]. *Health Devices Alerts* 2018 Jun 28 (Accession No. H0447).

Breaking badly: equipment failures from improper cleaning. *Health Devices* web conference 2018 Jun 27.

How improper cleaning can damage medical equipment. *Health Devices* 2017 Aug 16.

Improper cleaning may cause device malfunctions, equipment failures, and potential for patient injury. Hazard #5—top 10 health technology hazards for 2018. *Health Devices* 2017 Nov 1.

Skytron—various OR tables: power cord covers can minimize fire risk from liquid ingress into power receptacle [ECRI Exclusive Hazard Report]. *Health Devices Alerts* 2016 Dec 8 (Accession No. H0352).

10. Flawed Battery Charging Systems and Practices

FDA publishes battery survey results. *Health Devices* 2013 Nov 1.

Following are a sampling of reports related to insufficient battery charge that were issued through ECRI Institute's *Health Devices Alerts* notification service:

- BD—Alaris System PC units: low/very low battery alarm may not be triggered before the battery is discharged and all infusion channels are stopped. *Health Devices Alerts* 2017 Mar 22 (Accession No. A27499).
- Draeger—jaundice meters: battery may prematurely deteriorate. *Health Devices Alerts* 2017 Mar 2 (Accession No. A28107).
- Hamilton—HAMILTON-C2 and HAMILTON-C3 ventilators: batteries older than two years may fail. *Health Devices Alerts* 2017 Aug 31 (Accession No. A29141).
- Medtronic—rechargeable lithium-ion batteries used with Puritan Bennett 980 ventilator systems: may fail. *Health Devices Alerts* 2018 Jun 12 (Accession No. A29598). Also see: Medtronic—Puritan Bennett 980 ventilators: batteries may fail to charge [ECRI Exclusive Hazard Report]. *Health Devices Alerts* 2017 Oct 17 (Accession No. H0401).
- Owens & Minor—3M Professional 9681 surgical clippers: manufacturer adds product warning stressing proper charging practices to prevent lithium-ion battery degradation. *Health Devices Alerts* 2018 Feb 16 (Accession No. A30006 02).
- Philips—Lithium ion batteries used with IntelliVue patient monitors: manufacturer updates instructions for use. *Health Devices Alerts* 2017 Apr 11 (Accession No. A22127).
- Physio-Control—LIFEPAK 1000 defibrillators: software malfunction may lead to incorrect battery charge display; manufacturer reminds users of proper battery replacement instructions [Update]. *Health Devices Alerts* 2015 Sep 15 (Accession No. A22373 03).
- ZOLL—731 Series portable ventilators: battery may fail to charge when ventilator is off and plugged into AC power [ECRI Exclusive Hazard Report]. *Health Devices Alerts* 2016 Jul 20 (Accession No. H0316).

Objectives of the Health Devices System

To improve the effectiveness, safety, and economy of health services by:

- Providing independent, objective judgment for selecting, purchasing, managing, and using medical devices, equipment, and systems.
- Functioning as an information clearinghouse for hazards and deficiencies in medical devices.
- Encouraging the improvement of medical devices through an informed marketplace.

About ECRI Institute

For 50 years, ECRI Institute, a nonprofit organization, has been dedicated to bringing the discipline of applied scientific research to discover which medical procedures, devices, drugs, and processes are best, all to enable you to improve patient care. We firmly believe that seeking and finding the best ways to improve patient care require “The Discipline of Science” and “The Integrity of Independence.”

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