Top 10 Health Technology Hazards for 2017

A Report from *Health Devices*
November 2016

health.
DEVICES

ECRI Institute
The Discipline of Science. The Integrity of Independence.

Top 10 Health Technology Hazards for 2017

A Report from *Health Devices*
November 2016

Top 10 Health Technology Hazards for 2017

Executive Brief

ECRI Institute is providing this abridged version of its 2017 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 certain ECRI Institute programs through their membership web pages.

The List for 2017

1. Infusion Errors Can Be Deadly If Simple Safety Steps Are Overlooked
2. Inadequate Cleaning of Complex Reusable Instruments Can Lead to Infections
3. Missed Ventilator Alarms Can Lead to Patient Harm
4. Undetected Opioid-Induced Respiratory Depression
5. Infection Risks with Heater-Cooler Devices Used in Cardiothoracic Surgery
6. Software Management Gaps Put Patients, and Patient Data, at Risk
7. Occupational Radiation Hazards in Hybrid ORs
8. Automated Dispensing Cabinet Setup and Use Errors May Cause Medication Mishaps
9. Surgical Stapler Misuse and Malfunctions
10. Device Failures Caused by Cleaning Products and Practices

The Purpose of the List

The safe use of health technology—from basic infusion pumps to large, complex imaging 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. Additional content provided with the full article, which is available separately, provides guidance to help manage the risks. In this way, the list serves as a tool that healthcare facilities can use to prioritize their patient safety efforts.

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 members of some of our external advisory committees, 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 other topics should receive greater attention in 2017.

For Members Only: Log in to Access the Full Report and Solutions Kit

This Executive Brief helps raise awareness of critical health technology hazards—a key step in patient safety efforts. The next steps involve taking action to prevent the problems from occurring. The **2017 Top 10 Health Technology Hazards Solutions Kit**—available online to members of certain ECRI Institute programs—will help with that effort.

The Solutions Kit provides a comprehensive discussion of each topic, actionable recommendations for minimizing the risks of harm, and lists of useful resources for more information about each topic. The kit also provides online access to dozens of additional ECRI-exclusive member resources for addressing the hazards on this year's list. Members of ECRI Institute's Health Devices System, Health Devices Gold, and SELECTplus® programs can access this content through their membership web pages.

For information about becoming a member, contact clientservices@ecri. org or call +1 (610) 825-6000, ext. 5891. A list of related ECRI Institute resources for each topic is presented at the end of this report.

Infusion Errors Can Be Deadly If Simple Safety Steps Are Overlooked

Most large-volume infusion pumps incorporate safety mechanisms for reducing the risks of potentially deadly intravenous (IV) infusion errors. These mechanisms have greatly improved infusion safety, but can't eliminate all potential errors. And the mechanisms themselves have been known to fail.

ECRI Institute continues to learn about and investigate incidents of infusion errors involving pump or administration set failures, staff unknowingly defeating a safety mechanism, or incorrect infusion programming. Such errors—particularly those that result in the uncontrolled flow of medication to the patient, known as "IV free flow"—can lead to patient harm and even death.

In many of these incidents, harm could have been averted if staff had:

- Noticed signs of physical damage to infusion pump components
- Made appropriate use of the roller clamp on the IV tubing
- Checked the drip chamber beneath the medication reservoir for unexpected flow

Once commonplace, these simple practices are now often overlooked—perhaps because staff implicitly trust the pump's advanced safety features.

The use of contaminated medical instruments can lead to disabling or deadly patient infections or instrument malfunctions.

Outbreaks associated with the use of contaminated duodenoscopes—such as those that caused headlines in recent years—illustrate the severity of this issue. But duodenoscopes are not the only devices that warrant attention. ECRI Institute has received reports involving a variety of contaminated medical instruments that have been used, or almost used, on patients.

Complex, reusable instruments—such as endoscopes, cannulated drills, and arthroscopic shavers—are of particular concern. They can be difficult to clean and then disinfect or sterilize (i.e., reprocess) between uses, and the presence of any lingering contamination on, or in, the instrument can be difficult to detect.

Often, we find that inattention to the cleaning steps within the reprocessing protocol is a contributing factor. Healthcare facilities should verify that comprehensive reprocessing instructions are available to staff and that all steps are consistently followed, including precleaning of the device at the point of use.

2

Inadequate Cleaning of Complex Reusable Instruments Can Lead to Infections

Missed Ventilator Alarms Can Lead to Patient Harm

Ventilator alarm management challenges complicate efforts to prevent patient harm resulting from missed alarms. Ventilators deliver life-sustaining therapy, and a missed alarm could be deadly. Concerns include:

- Alarm fatigue—in which staff become overwhelmed by, distracted by, or desensitized to the number of alarms that activate.
- Alarm notification failures—in which alarms are not effectively communicated to staff.

These concerns, and the ways to manage them, are similar to those that exist with physiologic monitoring systems, which we have addressed in previous Top 10 Health Technology Hazards lists. Ventilators, however, pose some unique challenges. For example: Collecting and analyzing ventilator alarm data can be difficult, making it harder for hospitals to identify where their vulnerabilities lie. And the options for supplementing a ventilator's alarms—so that the alarm can be noticed outside the patient's room, for example—are limited.

As a result, ventilators will require different methods for studying the problem and different strategies for addressing it.

Patients receiving opioids—such as morphine, hydromorphone, or fentanyl—are at risk for drug-induced respiratory depression. If not detected, this condition can quickly lead to anoxic brain injury or death. Thus, spot checks every few hours of a patient's oxygenation and ventilation are inadequate.

Drug-induced respiratory depression is of particular concern for patients receiving parenteral and neuraxial opioids in medical-surgical and general care areas. However, it is also of concern for hospital or ambulatory surgery/endoscopy facility patients receiving opioids during procedural sedation and while in the postanesthesia care unit (PACU).

Even if they are otherwise healthy, such patients can be at risk if, for example:

- They are receiving another drug that also has a sedating effect
- They have diagnosed or undiagnosed sleep apnea or other conditions that predispose them to respiratory compromise
- They receive more medication than intended—for example, because of a medication error

ECRI Institute recommends that healthcare facilities implement measures to continuously monitor the adequacy of ventilation of these patients and has recently tested and rated monitoring devices for this application.

4

Undetected Opioid-Induced Respiratory Depression

Infection Risks with Heater-Cooler Devices Used in Cardiothoracic Surgery

5

Heater-cooler systems have been identified as a potential source of nontuberculous mycobacteria (NTM) infections in heart surgery. The likelihood of infection during surgery is not fully understood. However, these infections can be life-threatening and have resulted in patient deaths.

Heater-cooler systems are used in cardiothoracic surgeries to warm or cool the patient by extracorporeal heat exchange with the patient's blood during heart-lung bypass procedures. These devices circulate warm or cold water through a closed circuit. Water in the circuit is not intended to come into direct contact with the patient or the patient's circulating blood. However, aerosolized water carried by air from the exhaust vents of contaminated heater-coolers has been suggested as a cause of NTM infections.

Initial reports focused on one specific model of heater-cooler, but models from other suppliers could likewise become contaminated under certain circumstances and if appropriate precautions are not taken.

The U.S. Food and Drug Administration has issued recommendations for all heater-cooler devices; they are intended to help prevent and manage device contamination risks and to minimize patient exposure to heater-cooler exhaust air, which may contain aerosolized contaminated water.

Inadequate medical device software management can delay a facility's responses to safety alerts, allow cybersecurity vulnerabilities to be exploited, and impact patient safety.

Maintaining a central repository of up-to-date and easily retrievable information about the software versions used in a healthcare facility's medical devices is challenging. But failure to do so leaves the facility ill-prepared to effectively manage software updates and alerts.
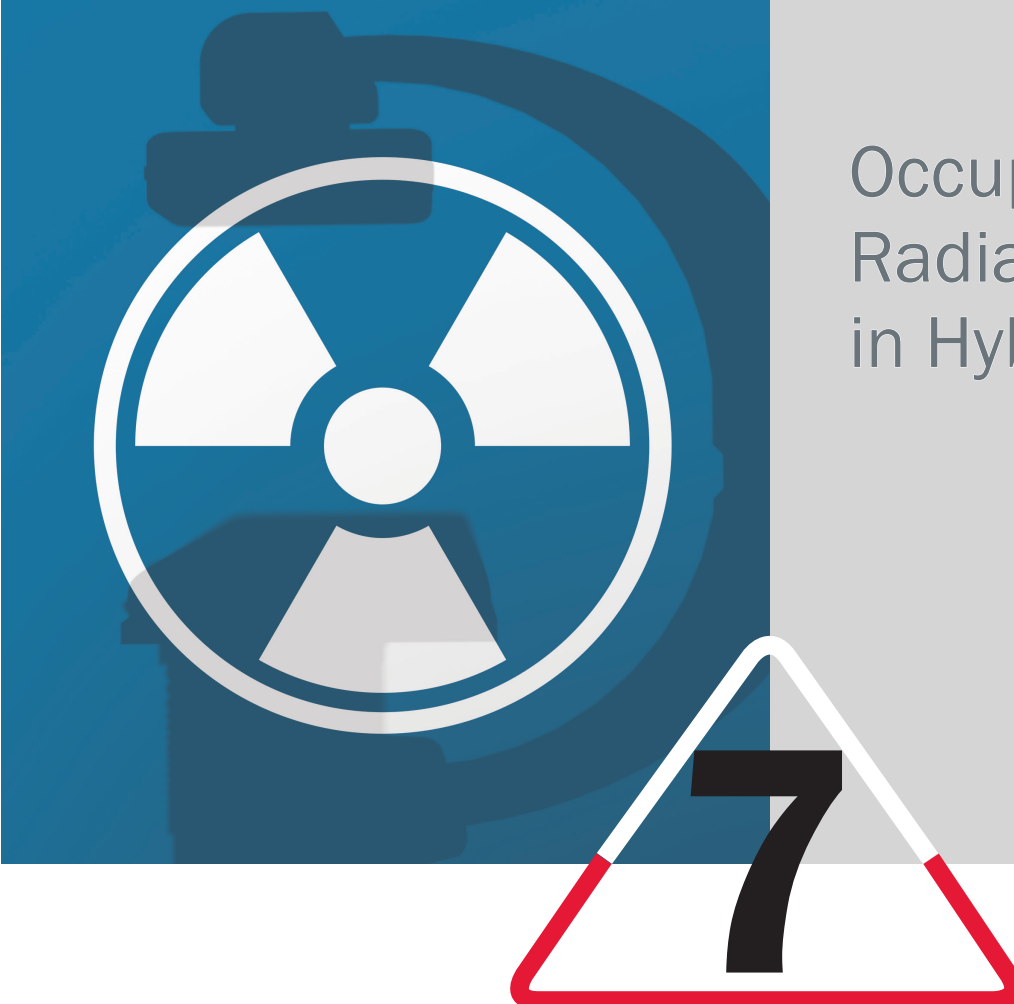
Mismanagement of software updates and alerts can adversely affect patient care or impact patient/staff safety—for example, by:

- Causing downtime or otherwise affecting the performance of medical devices or interconnected systems
- Delaying identification and implementation of key software updates, including those that address safety concerns
- Allowing cybersecurity vulnerabilities to persist, possibly leading to lost, stolen, or inaccessible data

To address the hazard, a healthcare facility should verify that its computerized maintenance management system (CMMS) provides the capabilities needed to effectively track software versions for its medical devices and systems. In addition, the facility should establish practices for keeping the software version information in the CMMS current and complete.

6

Software Management Gaps Put Patients, and Patient Data, at Risk

Occupational Radiation Hazards in Hybrid ORs

7

Clinicians working in hybrid ORs—operating suites that include built-in x-ray imaging systems—are at risk of unnecessary occupational exposures to ionizing radiation if appropriate precautions are not consistently followed.

Particular concern exists in this environment because hybrid OR staff may be less knowledgeable than radiology and interventional radiology staff about the risks of radiation exposure, and they may be less experienced at taking appropriate precautions.

In addition, with the increasing reliance on x-ray imaging systems during complex OR procedures, an increasing number of specialists and staff members who previously would have had little exposure to ionizing radiation during surgeries are now participating in these procedures.

Because long-term exposure to radiation increases the risk of cancer, it is imperative that hybrid OR staff obtain OR-specific radiation protection training, that they put this training into action, and that available tools and methods be used to minimize radiation exposures.

Poor choices made when setting up automated dispensing cabinets (ADCs), as well as mistakes made during use, can lead to harmful medication errors.

Medication errors and near misses associated with ADCs have been traced to insufficient planning when setting up medication drawers, as well as errors made when stocking them. Incidents reported to ECRI Institute include: the presence of the wrong drug or dose in an ADC pocket, the availability of high-alert drugs in unsecured areas of the cabinet, and the unavailability of needed drugs.

Problems such as these have resulted in delays in patient care and the administration of incorrect drugs or drug concentrations, leading in some cases to severe patient injury.

Careful planning is required to determine:

- Which medications should be available in a particular care area
- Where in the drawer a medication should be placed (e.g., to reduce the chances that one drug will be mistaken for another)
- Whether locked pockets or other control mechanisms should be used to further restrict access to certain medications

8

Automated Dispensing Cabinet Setup and Use Errors May Cause Medication Mishaps

Surgical Stapler Misuse and Malfunctions

9

Problems associated with the use and functioning of surgical staplers can lead to intraoperative hemorrhaging, tissue damage, unexpected postoperative bleeding, failed anastomoses, and other forms of patient harm.

Surgical staplers require meticulous technique to operate, and problems during use are not uncommon. The U.S. Food and Drug Administration receives thousands of adverse event reports related to surgical staplers each year, and ECRI Institute likewise consistently receives reports of surgical stapler problems. Although severe injuries are infrequent, they do occur: We have investigated fatalities and other cases of serious patient harm.

Commonly reported problems include: misfiring or difficulty in firing, misapplied staples, unusual sounds during firing (which can indicate a damaged or malfunctioning mechanism), and tissue becoming "jammed" in the mechanism.

To prevent patient harm, users must be familiar with device operation, they must carefully select the appropriate staple size for the patient and tissue type, and they must be alert to the signs that the stapler may not be functioning as intended.

The use of cleaning agents or cleaning practices that are incompatible with the materials used in a medical device's construction, or that are otherwise inappropriate for the device's design, can cause the device to malfunction or to fail prematurely, possibly affecting patient care. Specifically:

- Repeated use of incompatible cleaning agents can damage equipment surfaces and degrade plastics, often resulting in device breakage—possibly with no visible warning signs.
- The use of improper cleaning practices can damage seals, degrade lubricants, and cause fluid intrusion. This can result in damage to electronics, power supplies, and motors.

Because there is no single cleaner or cleaning process that will work with all devices, hospitals must stock and use multiple cleaning products and familiarize staff with device-specific cleaning methods—tasks that pose a significant burden. Nevertheless, failure to do so can lead to ineffective cleaning (a potentially deadly circumstance), as well as excessive component breakage and premature equipment failures (which can affect patient care and be a significant financial burden).

10

Device Failures Caused by Cleaning Products and Practices

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. Infusion Errors

Baxter—SIGMA Spectrum infusion pumps: incorrect technique for changing administration set may lead to unintentional free flow. *Health Devices Alerts* 2013 Sep 26 (Accession No. H0215).

CareFusion—Alaris pump modules: damaged door components may fail to engage anti free flow mechanism, potentially leading to gravity flow [ECRI Exclusive Hazard Report]. *Health Devices Alerts* 2016 Aug 25 (Accession No. H0337).

Hospira—Plum Series infusion pumps: close all upstream clamps to prevent primary and secondary fluid mixing when door is open [ECRI Exclusive Hazard Report]. *Health Devices Alerts* 2015 Nov 5 (Accession No. H0212 01).

Incorrect installation of free-flow clamp in B. Braun Infusomat Space infusion pumps may result in gravity flow. *Health Devices Alerts* 2011 Jan 13 (Accession No. H0134).

2. Inadequate Instrument Cleaning

ECRI Institute's guidance related to the reprocessing function:

— Use of unapproved brushes for cleaning endoscope channels is not recommended [ECRI Exclusive Hazard Report]. *Health Devices Alerts* 2016 Feb 11 (Accession No. H0306).

— 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.

— Duodenoscope reprocessing challenges lead to CRE exposures: update on a top 10 hazard. *Health Devices* 2015 Mar 11.

— Inadequate reprocessing of endoscopes and surgical instruments. Hazard #4—top 10 health technology hazards for 2015. *Health Devices* 2014 Nov 24.

— Clear channels: ensuring effective endoscope reprocessing. *Health Devices* 2010 Oct 1.

ECRI Institute's series of alerts pertaining specifically to the CRE infection issue:

— Endoscopic retrograde cholangiopancreatography (ERCP) duodenoscopes: design may impede effective cleaning. *Health Devices Alerts* 2015 Feb 20 (Accession No. H0245).

— ECRI Institute recommends culturing duodenoscopes as a key step to reducing CRE infections. *Health Devices Alerts* 2015 May 7 (Accession No. H0245 02).

— ECRI Institute provides perspectives on FDA's recent supplemental measures to enhance duodenoscope reprocessing. *Health Devices Alerts* 2015 Aug 7 (Accession No. H0245 03).

ECRI Institute's September 30, 2015, web conference:

Tracking scopes: best practices for identifying endoscopes during cleaning and patient use.

3. Missed Ventilator Alarms

Alarm hazards: inadequate alarm configuration policies and practices. Hazard #1—top 10 health technology hazards for 2015. *Health Devices* 2014 Nov 24.

Alarm Management Resources—This online resource page provides access to ECRI Institute's *Alarm Safety Handbook* and the accompanying *Alarm Safety Workbook*.

Evaluation background: ancillary alarm notification systems. *Health Devices* 2016 Sep 28. This resource provides an overview of, and links to, our evaluations of four ancillary alarm notification systems.

Interfacing monitoring systems with ventilators: how well do they communicate alarms? *Health Devices* 2012 May 1.

Missed alarms can have fatal consequences. Hazard #2—top 10 health technology hazards for 2016. *Health Devices* 2015 Nov 7.

Ventilator disconnections not caught because of misset or missed alarms. Hazard #5—top 10 health technology hazards for 2015. *Health Devices* 2014 Nov 24.

4. Opioid-Induced Respiratory Depression

ECRI Institute *Health Devices* product evaluations and guidance:

— Evaluation background: monitors for detecting respiratory depression—recommended for patients on opioids. *Health Devices* 2016 Oct 5.

— Evaluation: Masimo Root capnographic monitoring system—findings for detection of respiratory depression. *Health Devices* 2016 Oct 5.

— Evaluation: Medtronic Capnostream 20p monitor—findings for detection of respiratory depression. *Health Devices* 2016 Oct 5.

— Evaluation: Respiratory Motion ExSpiron 1Xi monitor—findings for detection of respiratory depression. *Health Devices* 2016 Oct 5.

— Failure to effectively monitor postoperative patients for opioid-induced respiratory depression can lead to brain injury or death. Hazard #3—top 10 health technology hazards for 2016. *Health Devices* 2015 Nov 7.

ECRI Institute PSO resources:

— Pain relief: how to keep opioid administration safe. *PSO Navigator* 2013 May.

— Patient risk factors for opioid-induced respiratory depression. PSO Research Response 2013 Jul.

5. Heater-Cooler Infection Risks

Sorin/LivaNova—3T heater-cooler systems: manufacturer announces plan to follow CDC and FDA recommendations. *Health Devices Alerts* 2016 Oct 20 (Accession No. A27411).

The S0287 series of Special Reports that culminated in S0287 02:

— Sorin/LivaNova—3T heater-cooler systems: FDA issues new recommendations related to *Mycobacterium chimaera* infection risks [update]. *Health Devices Alerts* 2016 Oct 14 (Accession No. S0287 02).

— Sorin—3T heater-cooler systems: FDA warns of *Mycobacterium chimaera* infections associated with use of systems. *Health Devices Alerts* 2016 Oct 13 (Accession No. S0287 01).

— Sorin—3T heater-cooler systems: FDA plans to restrict importation into U.S. *Health Devices Alerts* 2016 Jan 15 (Accession No. S0287).

Maquet—heater-cooler units: may become contaminated with bacteria. *Health Devices Alerts* 2016 Oct 5 (Accession No. A27329).

Bard—Medivance ARCTICSUN temperature management systems: manufacturer updates warnings to exclude use of in operating room. *Health Devices Alerts* 2016 Oct 24 (Accession No. A27250).

The A24508 series of Alerts that culminated in A24508 03:

— Sorin—heater cooler 1T and 3T devices: non-compliance with maintenance and disinfection instructions may yield contaminated water [update]. *Health Devices Alerts* 2016 Jun 21 (Accession No. A24508 03).

— Sorin—heater cooler 1T and 3T devices: non-compliance with maintenance and disinfection instructions may yield contaminated water [update]. *Health Devices Alerts* 2016 Jun 14 (Accession No. A24508 02).

— Sorin—heater cooler 1T and 3T devices: non-compliance with maintenance and disinfection instructions may yield contaminated water

[update]. *Health Devices Alerts* 2016 Aug 19 (Accession No. A24508 01).

— Sorin—heater cooler 1T and 3T devices: non-compliance with maintenance and disinfection instructions may yield contaminated water. *Health Devices Alerts* 2016 Aug 17 (Accession No. A24508).

Cincinnati Sub-Zero—Hemotherm dual-reservoir cooler-heaters and ECMO heaters: manufacturer reminds users of proper cleaning procedures to reduce risk of *Nontuberculous Mycobacterium* infections. *Health Devices Alerts* 2016 May 20 (Accession No. A25355).

FDA warns of nontuberculous mycobacterium infections associated with heater-cooler devices. *Health Devices Alerts* 2015 Oct 22 (Accession No. H0284).

Various heater-coolers used with cardiopulmonary bypass machines: may become contaminated with *Mycobacterium*, potentially leading to patient infection. *Health Devices Alerts* 2015 Jun 11 (Accession No. A24543).

Sorin—heater cooler devices: may become contaminated. *Health Devices Alerts* 2014 Aug 6 (Accession No. A22770).

6. Software Management Gaps

Biomed-IT collaboration critical to ensuring proper functioning of medical devices residing on hospital IT infrastructure. *Health Devices Alerts* 2013 Jun 6 (Accession No. S0241).

Failure to act on gamma camera manufacturer notices that require equipment servicing or modification can lead to serious patient injury or death. *Health Devices Alerts* 2015 Jun 11 (Accession No. H0259).

Hospira—MedNet Medication Management Suite used with SapphirePlus infusion pumps: incorrect bolus amounts may be calculated for specific drugs. *Health Devices Alerts* 2016 Sep 29 (Accession No. A27131).

Neglecting change management for networked devices and systems. In: Top 10 health technology hazards for 2014: key safety threats to manage in the coming year (Hazard #7). *Health Devices* 2013 Nov 1.

Varian—ARIA Radiation Therapy Management Prescribe Treatment software: organ at risk dose-volume constraint values may be displayed incorrectly if prescription was created in previous version. *Health Devices Alerts* 2016 Sep 15 (Accession No. A27200).

Windows 10 upgrade may result in medical device malfunction. *Health Devices Alerts* 2015 Dec 10 (Accession No. H0296).

7. Occupational Radiation Hazards in Hybrid ORs

Occupational radiation hazards in hybrid ORs (Hazard No. 5). In: Top 10 health technology hazards for 2014: key safety threats to manage in the coming year. *Health Devices* 2013 Nov 1.

8. Automated Dispensing Cabinet Errors

Medication management systems, decentralized. *Healthcare Product Comparison System* 2014 Nov.

9. Surgical Stapler Misuse and Malfunctions

Before a surgical stapler fails [guidance article]. *Health Devices* 2001 Oct.

Surgical staplers: recommendations to reduce the risk of commonly reported problems. *Health Devices Alerts* 2016 Mar 17 (Accession No. H0312).

Surgical stapler hazards. In: Top 10 technology hazards: high-priority risks and what to do about them (Hazard #8). *Health Devices* 2009 Nov.

Using the wrong size surgical stapler cartridge can injure patients [hazard report]. *Health Devices* 2009 Apr.

10. Device Failures Caused by Cleaning Products and Practices

Baxter—SIGMA Spectrum infusion pumps: incorrect cleaning of pump battery connections may lead to battery alarms and errors. [ECRI Exclusive Hazard Report]. *Health Devices Alerts* 2015 Sep 10 (Accession No. H0274).

Berchtold—OPERON surgical table hand controls: unintended table section movement may occur [Update]. *Health Devices Alerts* 2014 Jul 31 (Accession No. A19816 01).

Covidien/Medtronic—Genius 2 ear tympanic thermometers: may crack from use of incompatible disinfectants. [ECRI Exclusive Hazard Report]. *Health Devices Alerts* 2015 Sep 10 (Accession No. H0275).

ECRI Institute User Experience Network—lower door hinge may crack on Carefusion Alaris 8100 Pump Modules. *Health Devices Alerts* 2014 May 15 (Accession No. S0251 01).

Fresenius—2008 series hemodialysis machines: manufacturer reminds users of cleaning guidelines. *Health Devices Alerts* 2015 Aug 12 (Accession No. A24922).

Haemonetics—various cell processor and collection system devices: improper cleaning may damage pump rollers, potentially leading to device malfunction [Update]. *Health Devices Alerts* 2016 Feb 23 (Accession No. A25476 01).

Infusion pumps—failure to follow manufacturers' recommended cleaning instructions may cause premature device failures. [ECRI Exclusive Hazard Report]. *Health Devices Alerts* 2016 Jun 16 (Accession No. H0328).

Intuitive—da Vinci Surgical Systems: certain disinfectant wipes may damage instrument arm plastic components. *Health Devices Alerts* 2016 Jan 14 (Accession No. A25621).

PARI—PARI SOLE N and PARI SOLE N Tracheo inhalation devices: liquid may damage temperature gauge. *Health Devices Alerts* 2013 Nov 12 (Accession No. A21201).

Philips M4841a telemetry transmitters may experience short circuit and overheat if battery compartment tab breaks. [Hazard Report]. *Health Devices Alerts* 2013 Feb 28 (Accession No. H0192).

Siemens—cleaning solutions used with ADVIA Centaur Systems: hypochlorite may degrade at a higher-than-expected rate. *Health Devices Alerts* 2014 Nov 26 (A23371).

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.

ECRI Institute
The Discipline of Science. The Integrity of Independence.

▷ **UNITED STATES**
5200 Butler Pike
Plymouth Meeting, PA
19462-1298, USA
Telephone +1 (610) 825-6000
Fax +1 (610) 834-1275

▷ **EUROPE**
Suite 104, 29 Broadwater Road
Welwyn Garden City
Hertfordshire, AL7 3BQ, UK
Telephone +44 (1707) 871 511
Fax +44 (1707) 393 138

▷ **ASIA PACIFIC**
11-3-10, Jalan 3/109F
Danau Business Centre
Taman Danau Desa
58100 Kuala Lumpur, Malaysia
Telephone +60 3 7988 1919
Fax +60 3 7988 1170

▷ **MIDDLE EAST/ICME**
Office 708-6, Fairmont Hotel
Sheikh Zayed Road
P.O. Box 128740
Dubai, United Arab Emirates
Telephone +971 4 3042460
Fax +971 4 3042461