

EXECUTIVE BRIEF

Top 10 Health Technology Hazards for 2016

A Report from *Health Devices*
November 2015



health
DEVICES

ECRI Institute
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Top 10 Health Technology Hazards for 2016

EXECUTIVE BRIEF

ECRI Institute is providing this abridged version of its 2016 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 is available to members of certain ECRI Institute programs through their membership web pages and to others through the Solutions Kit described in the inset on the next page.

THE LIST FOR 2016

1. Inadequate Cleaning of Flexible Endoscopes before Disinfection Can Spread Deadly Pathogens
2. Missed Alarms Can Have Fatal Consequences
3. Failure to Effectively Monitor Postoperative Patients for Opioid-Induced Respiratory Depression Can Lead to Brain Injury or Death
4. Inadequate Surveillance of Monitored Patients in a Telemetry Setting May Put Patients at Risk
5. Insufficient Training of Clinicians on Operating Room Technologies Puts Patients at Increased Risk of Harm
6. Errors Arise When HIT Configurations and Facility Workflow Do Not Support Each Other
7. Unsafe Injection Practices Expose Patients to Infectious Agents
8. Gamma Camera Mechanical Failures Can Lead to Serious Injury or Death
9. Failure to Appropriately Operate Intensive Care Ventilators Can Result in Preventable Ventilator-Induced Lung Injuries
10. Misuse of USB Ports Can Cause Medical Devices to Malfunction

THE PURPOSE OF THE LIST

The safe use of health technology—from syringes to bedside patient monitors to health 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. 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, and
- ▷ 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 2016.

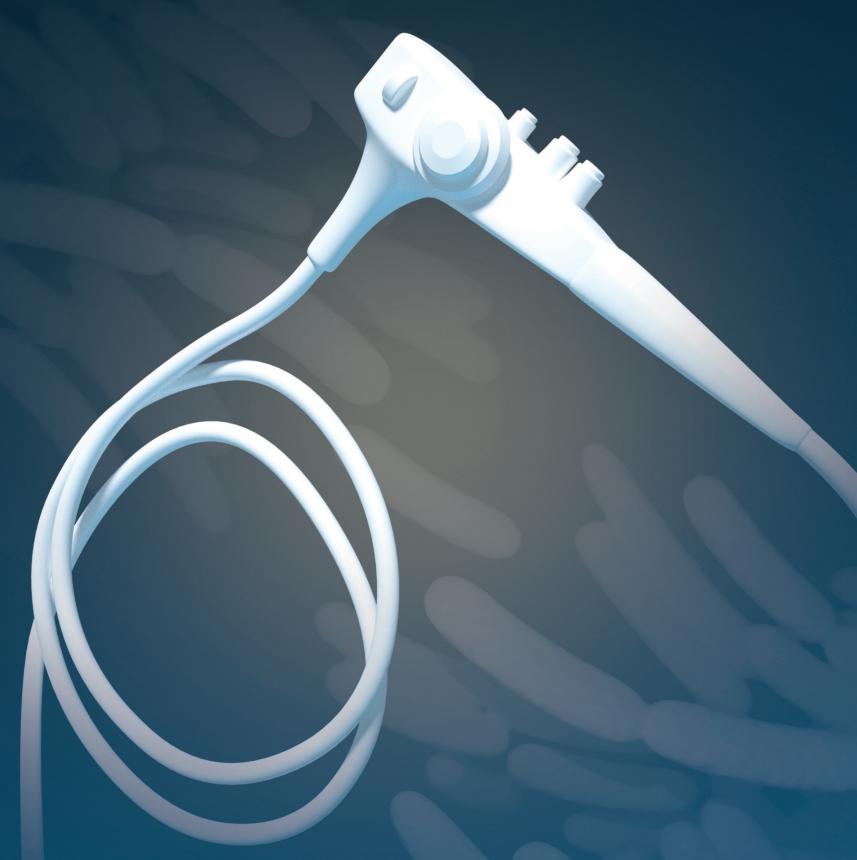
Need Help? Check Out Our Solutions Kit

Awareness of critical health technology hazards is a key first step. The next steps involve taking action to prevent the problems from occurring.

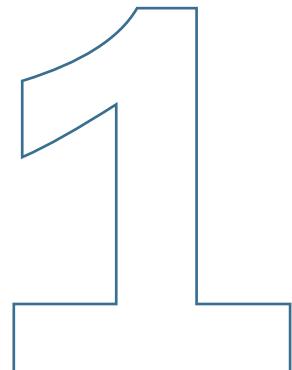
If you're interested in resources for addressing the problems described in this report, check out our **2016 Top 10 Health Technology Hazards**

Solutions Kit. The 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. In addition, the Solutions Kit 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 already access this content through their membership pages.)

For more information, contact clientservices@ecri.org or call +1 (610) 825-6000, ext. 5891, or visit www.ecri.org/hazardsolutions.



Inadequate Cleaning of Flexible Endoscopes before Disinfection Can Spread Deadly Pathogens



The failure to adequately reprocess contaminated instruments—that is, to clean and disinfect or sterilize them—before using them on subsequent patients can lead to the spread of deadly pathogens.

A key aspect of effective reprocessing is cleaning biologic debris and other foreign material from instruments before the disinfection or sterilization step. If this precleaning is not carried out effectively, the disinfection or sterilization step may not be effective.

Flexible endoscopes in general, and duodenoscopes in particular, are of specific concern because their complex design and long, narrow channels can make effective cleaning difficult. A series of fatal carbapenem-resistant Enterobacteriaceae (CRE) infections that attracted a lot of attention in 2014 and 2015 illustrates this concern: The deaths were associated with the use of duodenoscopes that had not been successfully disinfected between uses.

Facilities need to emphasize to their reprocessing staff that inattention to the cleaning steps within the reprocessing protocol can lead to deadly infections.

2



Missed Alarms Can Have Fatal Consequences

Failure to recognize and respond to an actionable clinical alarm condition in a timely manner can result in serious patient injury or death.

Patients are put at risk:

- ▷ When an alarm condition is not detected by a medical device (such as a physiologic monitor, ventilator, or infusion pump)
- ▷ When the condition is detected, but not successfully communicated to a staff member who can respond
- ▷ Or when the condition is communicated to clinical staff, but not appropriately addressed—whether because staff fail to notice the alarm, choose to ignore an alarm that warrants a response, or otherwise respond incorrectly

Addressing clinical alarm hazards in all their forms requires a comprehensive alarm management program that includes stakeholders from throughout the organization.



Failure to Effectively Monitor Postoperative Patients for Opioid-Induced Respiratory Depression Can Lead to Brain Injury or Death

3

Hospitalized patients receiving postoperative opioids—such as morphine, hydromorphone, or fentanyl—are at risk for drug-induced respiratory depression, which can lead to anoxic brain injury or death.

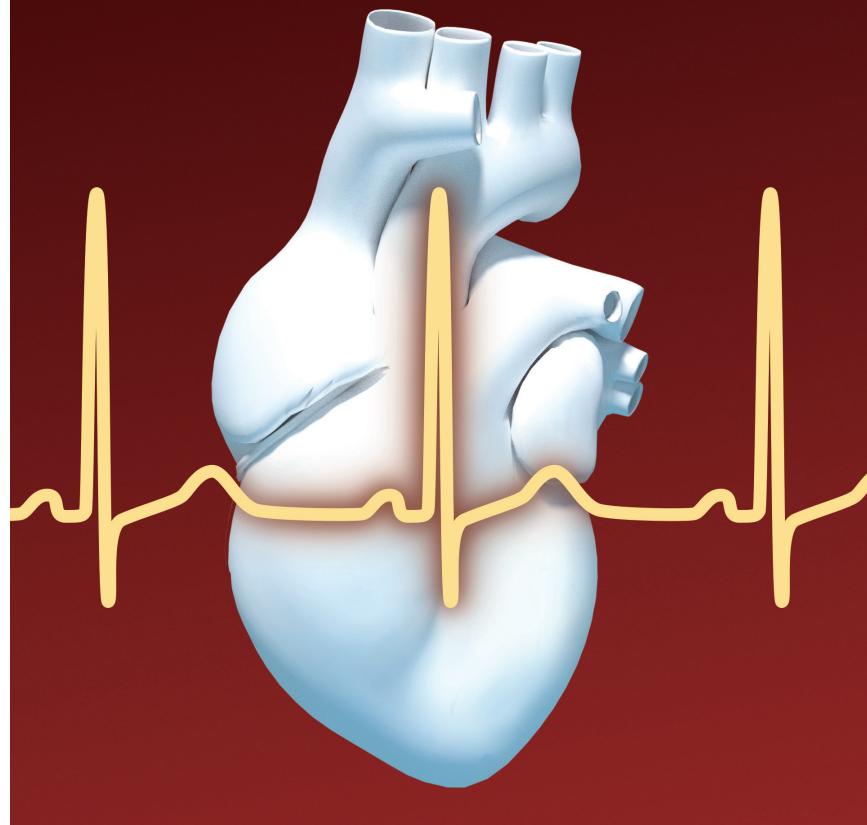
Even if they are otherwise healthy, such patients can be at risk if, for example:

- ▷ They are receiving another drug that also has a sedating effect.
- ▷ They have diagnosed or undiagnosed comorbidities that predispose them to respiratory compromise, such as morbid obesity or sleep apnea.
- ▷ A medication error results in delivery of more medication than intended—for example, an error is made when programming the dose or concentration on the infusion pump, or a bag or syringe of the wrong concentration or wrong medication is used.

Intermittent spot checks of oxygenation and ventilation every few hours are inadequate for reliably detecting opioid-induced respiratory depression.

To address this problem, a healthcare facility's medical leadership should implement the relevant recommendations from the Anesthesia Patient Safety Foundation (APSF) and the Joint Commission.

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Inadequate Surveillance of Monitored Patients in a Telemetry Setting May Put Patients at Risk

Inadequate surveillance of monitored patients in telemetry settings can lead to unrecognized critical events and subsequent patient harm. Factors that can contribute to this problem include:

- ▷ The incorrect assumption that monitoring systems can reliably detect all potentially lethal arrhythmias
- ▷ The trend toward using telemetry monitoring with sicker patients than in the past and in care areas where patients are not as closely supervised (e.g., areas with higher nurse-to-patient ratios)
- ▷ The display of patient monitoring information solely at the central station, where events may be missed if staff are not present to observe the patient waveforms and data or if they are distracted with other tasks

Consequences include serious patient injury or death.

Alleviating this problem entails educating appropriate personnel about the limitations of monitoring technology and the factors that could lead to missed events, as well as implementing measures to improve patient surveillance.



5

Insufficient Training of Clinicians on Operating Room Technologies Puts Patients at Increased Risk of Harm

Insufficient training of clinicians on operating room (OR) technologies can result in use errors that lead to prolonged surgery, complications that require additional treatment, and even serious patient injury or death.

Errors can result if training:

- ▷ Is not provided or is insufficient or ineffective (e.g., if it does not provide an assurance of competency)
- ▷ Does not include all relevant team members, including physicians, per diem staff, and new hires, as well as regular staff
- ▷ Is not completed by all relevant team members before they use a device in clinical practice

ECRI Institute estimates that approximately 70% of accidents involving a medical device can be attributed to user error or the technique of use. Many of these incidents could have been avoided if users had a better understanding of the instructions for use and device operation.

Facilities should make training a key part of the acquisition process for new OR technologies, as well as an ongoing consideration for existing technologies.

6

Errors Arise When HIT Configurations and Facility Workflow Do Not Support Each Other

Poor alignment between the configuration of a health IT (HIT) system and a facility's workflow increases the opportunity for medical errors, putting patients at risk. Problems can arise if the HIT system is not configured to support the processes and workflow used in a particular care area, or if the workflows and standard operating procedures are not adjusted to accommodate the capabilities of HIT systems.

This can lead to issues such as:

- ▷ Missed information or the inability to find needed information within the HIT system
 - ▷ The mistaken application of default values—for dosing, time, or orders—instead of the desired values
 - ▷ Input errors
 - ▷ The use of workarounds

Any of the above problems can result in patient harm due to delayed, incorrect, or undelivered therapies.

Facilities should consider configuration issues during the HIT system selection phase and should modify and validate workflows to confirm that they align with the system's capabilities.



Unsafe Injection Practices Expose Patients to Infectious Agents

Unsafe injection practices are an ongoing patient safety concern, both in hospitals and in outpatient settings. Far too often, incidents occur leading to the transmission of bloodborne viruses, the spread of bacterial infections, and potential exposures that require notifying large numbers of patients about the threat to their health.

Some practices that put patients at risk are:

- ▷ Reusing a needle or syringe that had been used to administer medication
- ▷ Sharing an insulin pen among patients (even if a new needle is used)
- ▷ Using a single-dose medication vial for multiple patients
- ▷ Failing to use aseptic technique when preparing, handling, and injecting medications

Cross-contamination resulting from unsafe injection practices has led to:

- ▷ Disease transmission, causing patient illness or death
- ▷ Damage to the healthcare facility's reputation, its financial health, or its accreditation status
- ▷ Criminal prosecution resulting in penalties and, in some cases, imprisonment for the responsible healthcare professionals

Solutions involve action by frontline healthcare workers, by the leadership of hospitals, outpatient clinics, and skilled nursing facilities, and by patients.

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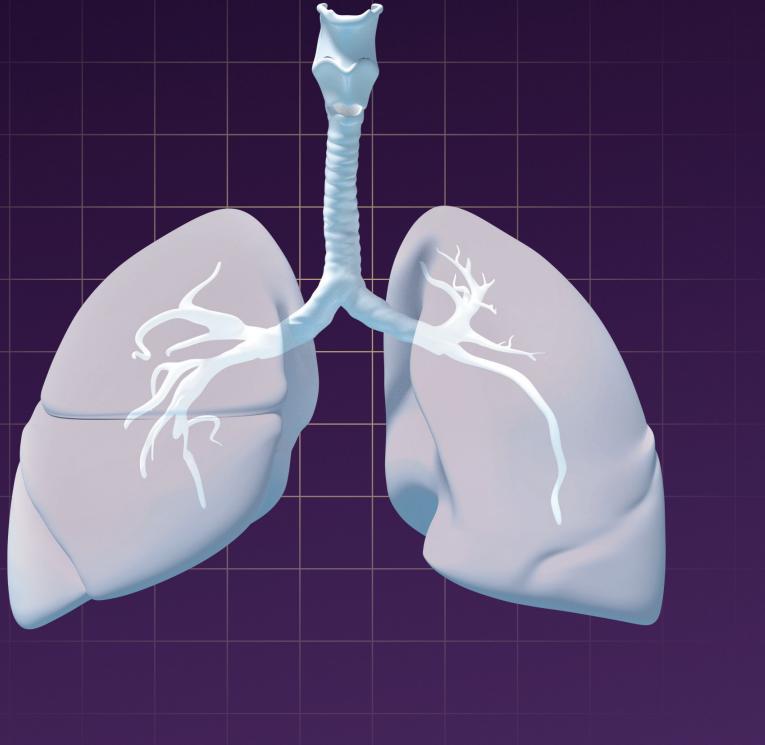
Gamma Camera Mechanical Failures Can Lead to Serious Injury or Death

Gamma cameras incorporate heavy, moving components that can cause significant harm if they rotate into or fall onto a patient or staff member. ECRI Institute and FDA have received multiple reports of mechanical failures involving gamma cameras that had caused serious—and in one case fatal—injuries.

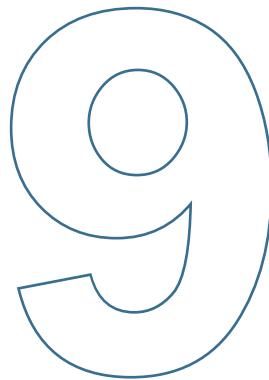
- ▷ Such failures can occur when gamma camera systems are not maintained properly.
- ▷ A notable concern is the fact that safety-related recalls are not always addressed in a timely manner, which can allow a hazardous situation to develop.

With more than 40 gamma camera safety recalls having been filed with FDA in a recent two-year period, incidents could occur at any healthcare facility that lacks an effective process for handling gamma camera recalls.

Facilities should advise staff not to leave patients unattended in the gamma camera scan room. They should also maintain, service, and inspect gamma cameras in accordance with the manufacturer's guidance, and verify that all current recalls and safety notices have been acted on.



Failure to Appropriately Operate Intensive Care Ventilators Can Result in Preventable Ventilator-Induced Lung Injuries



Inappropriate patient ventilation can cause ventilator-induced lung injury (VILI), particularly in intensive care patients, and may lead to patient death. Lung-protective strategies (e.g., using lower tidal volumes) have been developed, and advanced ventilator modes and features are available to aid clinicians in providing safer and more effective ventilation. Too often, however:

- ▷ These existing techniques and tools are not used to their full advantage.
- ▷ Best practices and device capabilities are not assessed and adopted, when warranted.

Factors that contribute to the inadequate implementation of safer and more effective ventilation strategies include:

- ▷ A lack of continuing education on the best practices for patient ventilation
- ▷ Insufficient understanding of complex ventilator functionality
- ▷ Inconsistent terminology among ventilator manufacturers, leading to potential confusion among clinical practitioners

Facilities can alleviate these issues by confirming that all staff involved with mechanical ventilation have a sound understanding of the devices and their use.

10



Misuse of USB Ports Can Cause Medical Devices to Malfunction

Plugging unauthorized devices or accessories into USB ports on medical devices can cause the medical devices to malfunction. Direct effects on medical device operation—for example, causing a physiologic monitor to reboot—have been observed in clinical practice.

Possible problems include instances in which:

- ▷ The device shuts down, and the patient does not receive therapy.
- ▷ The device settings are changed or performance is compromised.
- ▷ A patient monitor ceases to monitor the patient or fails to alarm for problems that require attention.

Uncontrolled access to medical device USB ports could also lead to a security breach, putting the patient's data and the healthcare facility's systems at risk.

Facilities need to develop and implement a policy on the appropriate use of USB ports on medical devices.

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. Endoscope Reprocessing

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

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

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

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

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

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

Web conference:

Tracking scopes: best practices for identifying endoscopes during cleaning and patient use (September 30, 2015).

2. Missed Alarms

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

Alarm safety handbook and *Alarm safety workbook*. ECRI Institute 2014.

Central station and auxiliary alarms—inaudibility continues to contribute to missed alarms. *Health Devices Alerts* 2015 Jul 16 (Accession No. H0264).

How the Children's Hospital of Philadelphia used video to better understand alarm fatigue. *Health Devices* 2015 Feb 4.

Inappropriately configured ancillary alarm notification systems may result in missing critical alarms. *Health Devices Alerts* 2014 Nov 20 (Accession No. H0242).

Over-reliance on arrhythmia detection algorithms in physiologic monitoring systems puts patients on telemetry at risk. *Health Devices Alerts* 2015 Jun 12 (Accession No. H0261).

Preventing the overuse of cardiac telemetry monitoring—Christiana Care Health System's award-winning project. *Health Devices* 2015 Jan 14.

Web conferences:

- Lessons learned on the use of telemetry (June 17, 2015).
- Alarm middleware vendor roundtable: cutting through the confusion (April 29, 2015).
- Good alarm policies are no accident (September 3, 2014).
- Answering the call to alarm safety: getting ready for Joint Commission's National Patient Safety Goal (August 14, 2013).

3. Monitoring Postsurgical Patients on Opioids

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.

4. Inadequate Surveillance of Telemetry Patients

Considering a monitor watcher program? Be aware of the challenges. *Health Devices* 2015 Sep 16.

Improving patient surveillance in telemetry: don't just rely on the monitor. *Health Devices* 2015 Sep 16.

Over-reliance on arrhythmia detection algorithms in physiologic monitoring systems puts patients on telemetry at risk. *Health Devices Alerts* 2015 Jun 12 (Accession No. H0261).

Preventing the overuse of cardiac telemetry monitoring—Christiana Care Health System's award-winning project. *Health Devices* 2015 Jan 14.

5. Insufficient Training on OR Technologies

Ethicon—HARMONIC ACE+ Shears: tissue pad may detach if shears are activated without tissue in jaws. *Health Devices Alerts* 2015 Jul 25 (Accession No. H0266).

Keeping score: health system closely tracks outcomes of surgical procedures using robotic equipment. *Operating Room Risk Management News* 2013 Nov 15.

New clinical guide to surgical fire prevention: patients can catch fire—here's how to keep them safer. *Health Devices* 2009 Oct 1.

Robotic surgery: complications due to insufficient training. Hazard #8—top 10 health technology hazards for 2015. *Health Devices* 2014 Nov 24.

6. HIT Configurations and Workflow

The basics of EMR integration. *Health Devices* 2014 Jan 2.

Data integrity: incorrect or missing data in EHRs and other health IT systems. Hazard #2—top 10 health technology hazards for 2015. *Health Devices* 2014 Nov 24.

How to connect with the right EMR integration vendor. *Health Devices* 2014 Jan 2.

Making connections: integrating medical devices with electronic medical records. *Health Devices* 2012 Apr 1.

7. Unsafe Injection Practices

The full article cites resources from various organizations.

8. Gamma Camera Mechanical Failures

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).

9. Failure to Appropriately Operate Ventilators

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

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.

10. Misuse of USB Ports

Cybersecurity: insufficient protections for medical devices and systems. Hazard #9—top 10 health technology hazards for 2015. *Health Devices* 2014 Nov 24.

GE—CARESCAPE B650 and B850 bedside monitors with software version 1.0.12: may spontaneously reboot if a device is connected to USB port. *Health Devices Alerts* 2015 Aug 19 (Accession No. H0273).

Spacelabs—ARKON Anesthesia Delivery Systems: may enter controlled failed state. *Health Devices Alerts* 2014 Apr 18 (Accession No. A22147).

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.

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