



Medical Technology and Patient Safety with a Focus on ECRI Institute's Top Ten Hazards

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Presentation Overview

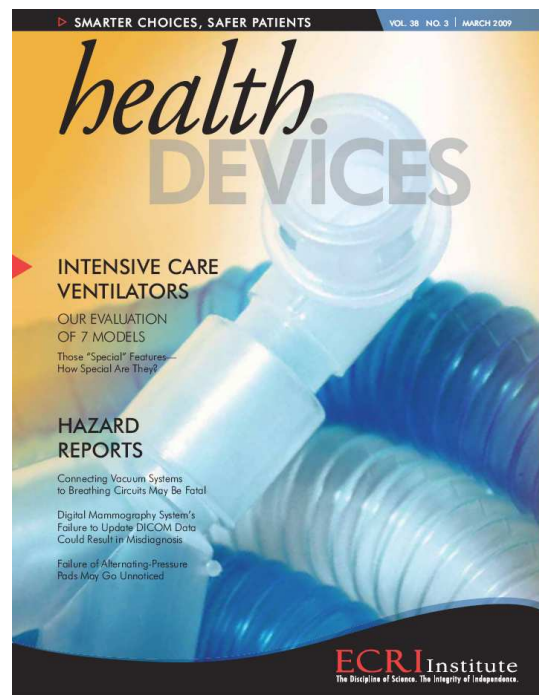
- ▶ ECRI Institute/ECRI overview
- ▶ Survey of the landscape
- ▶ Review of ECRI Institute's "Top Ten" list
- ▶ Management of hazards and recalls
- ▶ Information technology – a new safety concern
- ▶ Key measures for improving medical device-related safety and reducing associated liability
- ▶ Useful references



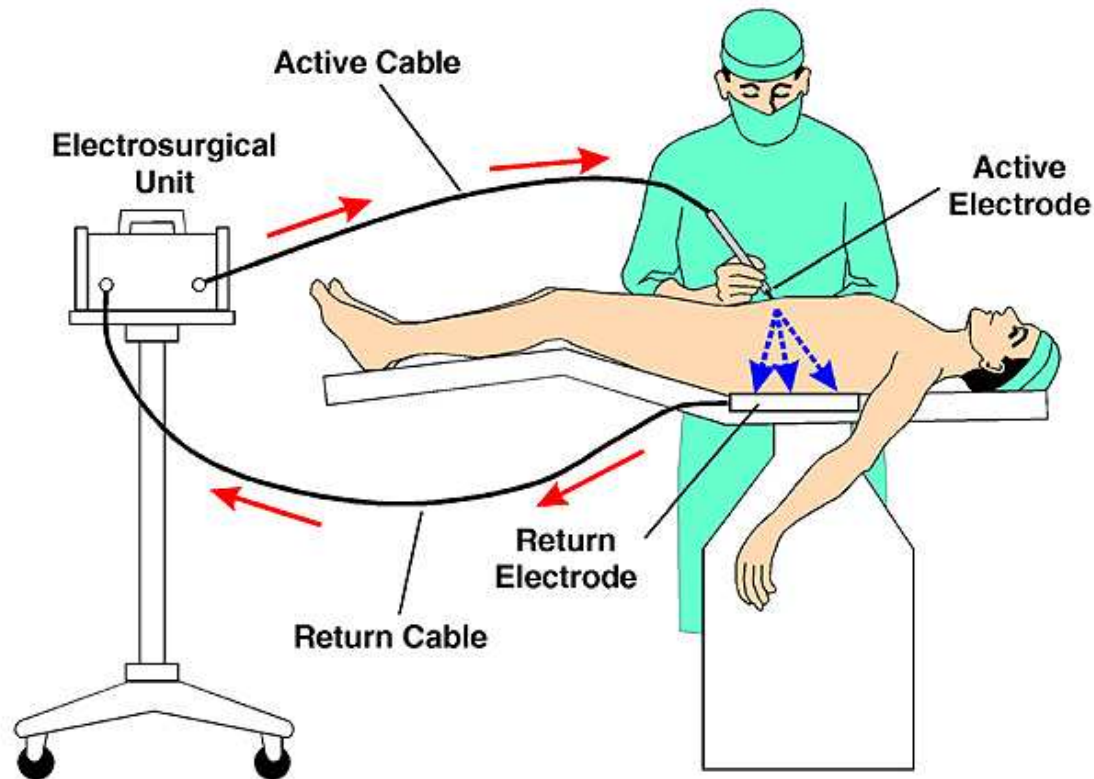
ECRI Institute Background

- ▶ ECRI Institute is a nonprofit healthcare research organization. Our mission is to enable healthcare organizations to improve patient care. For 40 years we have dedicated ourselves to this mission, bringing the discipline of scientific research to discover which approaches are best.
- ▶ In a phrase, “ECRI Institute is an independent non-profit that researches the best approaches to improving patient care”

Health Devices Evaluations and Guidance



Typical Problem - Close to Home



Survey of the Landscape

- ▶ Wide variety of technologies (disposables to multi-parameter interconnected instruments)
- ▶ Increasing complexity of technology
- ▶ Poor planning for new technology, which results in poor implementation of technology
- ▶ Inadequately trained users
- ▶ Lack of standardization
- ▶ Etc.

Medical Device-Related Safety Analyses

- ▶ *Health Devices* Consumer Reports-like comparative evaluations
- ▶ International problem reporting system
- ▶ Accident and forensic investigation program
- ▶ Consultation and advisory services
- ▶ Standards development and other research
- ▶ General experience

Top Ten List of Hazards

- ▶ Historical analysis
- ▶ Health technology-related hazards that should be on every hospital's "to-do" list to address
- ▶ Focus on prevalence and severity of reported events
- ▶ Similar in concept to widely reported "Never Events"
- ▶ Get the word out about important and preventable safety problems
- ▶ Published in *Health Devices* (November 2007 and 2008)

Top 10 Health Technology Hazards



Health Devices 2008 Top Ten List

1. Alarm hazards
2. Needlesticks and other sharps injuries
3. Air embolism from contrast media
4. Retained devices and unretrieved fragments
5. Surgical fires
6. Anesthesia hazards from inadequate pre-use Inspection
7. Misleading displays
8. CT radiation dose
9. MR imaging burns
10. Fiberoptic light-source burns

Typical Incident From Critical Care

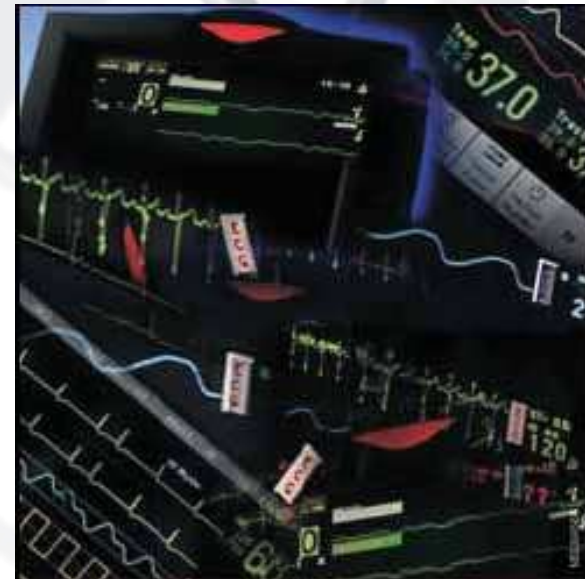
- ▶ Ventilator-dependent patient – frequent coughing
- ▶ Coughing triggers high-pressure alarm
- ▶ Frequent response to alarm by nurse with no real problem
- ▶ Pressure alarm limit increased to minimize the number of false-positive alarms
- ▶ An accident waiting to happen
 - Patient movement crimps breathing circuit
 - Secretions clog the endotracheal tube
 - Inadequate ventilation (inhalation or expiration)

Some Questions to Ask

- ▶ Does the nurse understand the purpose of the high-pressure alarm?
- ▶ Was the nurse's competence in ventilator use validated?
- ▶ Does the hospital have a policy for who can and cannot set ventilator alarms?
- ▶ Is there a policy on how ventilator alarms should be set?
 - If so, is it generic or does it consider specific circumstances?
 - Does the hospital have ventilator responsive-valve features, which can reduce nuisance high-pressure alarms?

1. Alarm Hazards

- ▶ Among most frequently reported problems
- ▶ Monitoring equipment, ventilators, dialysis units, and many other devices
- ▶ Failure to respond, missed events, complexity of controls, apparent similarity of different model devices, user training, environmental factors



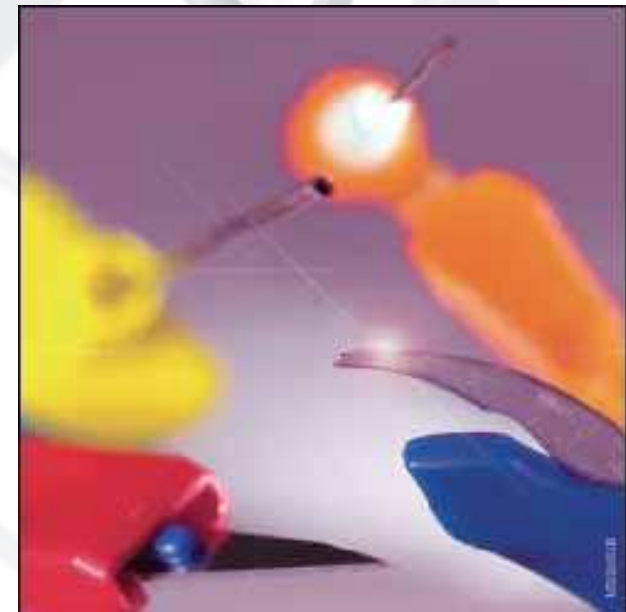
Clinical Alarm Safety

To-Do List

- ▶ Evaluate how alarms are used and set in your institution
 - Establish clear protocols for alarm setting and use
- ▶ Know your devices and systems and communicate your knowledge to clinical staff
 - Knowledge of subtle device performance characteristics can have a big safety impact
- ▶ Evaluate environmental factors that can affect alarm performance and response
 - Identify immediate technology and process solutions

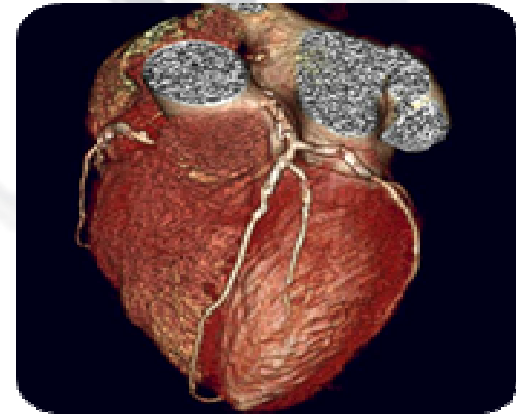
2. Needlesticks and Other Sharps Injuries

- ▶ Most hospitals should have deployed needlestick prevention devices
- ▶ Injuries continue to occur (e.g. protection may not be very good or protective features not used)
- ▶ Consequences from needlesticks can be severe
- ▶ Careful device selection and training with new devices is key



3. Air Embolism from Contrast Media

- ▶ Increasing use of power contrast injectors
- ▶ High power injection creates risk of dangerous emboli
- ▶ Most injectors have air detectors but they are not foolproof
- ▶ Staff must make sure that protections are installed and enabled
- ▶ Tubing inspections are key



5. Surgical Fires

- ▶ Relatively uncommon but serious and high profile (e.g., *Wall Street Journal*)
- ▶ Control needed for ignition source, oxygen supply, and fuel source (e.g., limit oxygen level to as low a percentage as possible)
- ▶ Constant vigilance and staff awareness are key



Fire Scenario









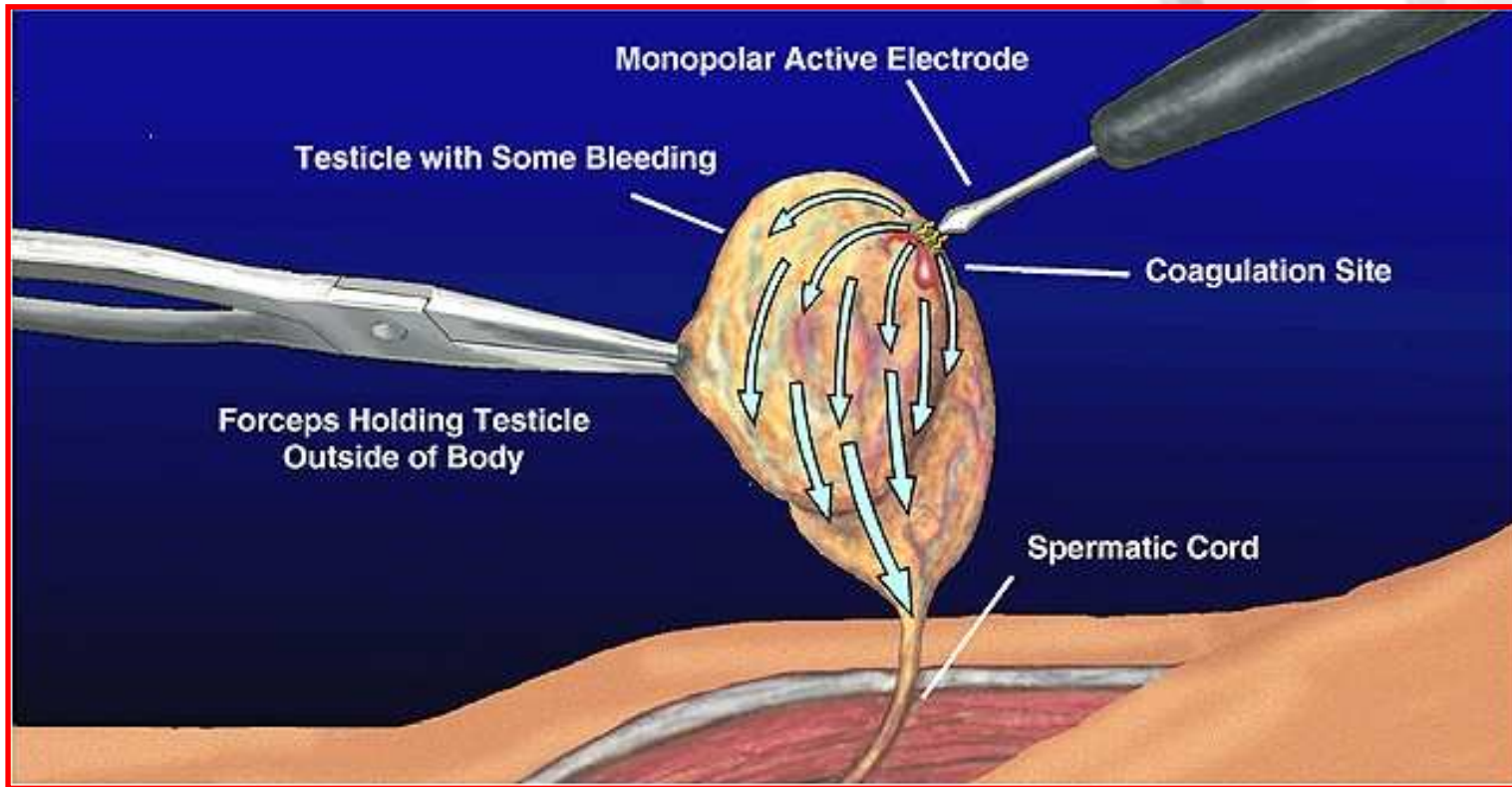


Burns During Electrosurgery

- ▶ Many reported incidents over many years
- ▶ Dozens of articles warning of risk
- ▶ Ubiquitous and difficult to understand technology
- ▶ Some really simple and effective solutions (e.g., holsters, dual plate pads, active electrode monitoring during laparoscopy)



A Scary User-Related Problem



Spermatic Cord Damage from Electrosurgery

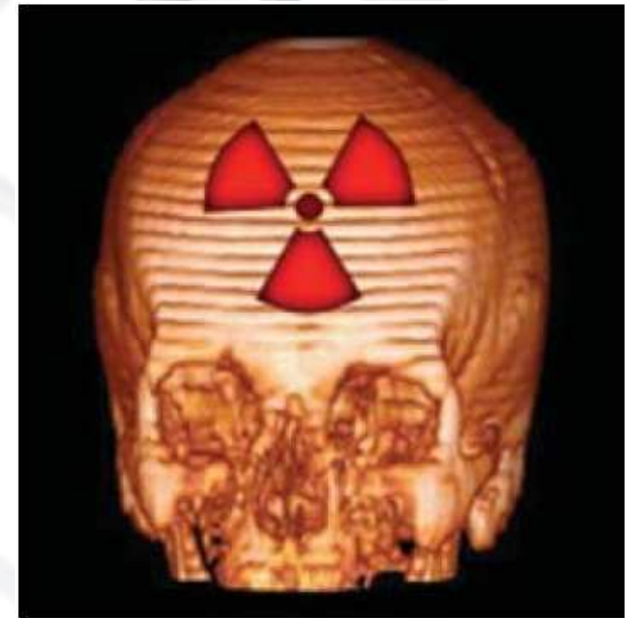
8. CT Radiation Dose

- ▶ CT is used more and more every day
- ▶ Many prescribing clinicians are not aware of CT dose risks
- ▶ In the US, CT may be responsible for about 6,000 additional cancers (half are fatal) *
- ▶ Exams should be justified and scanning protocols should be optimized
- ▶ CT quality control is key

* *Health Devices*, Vol. 36, No. 2

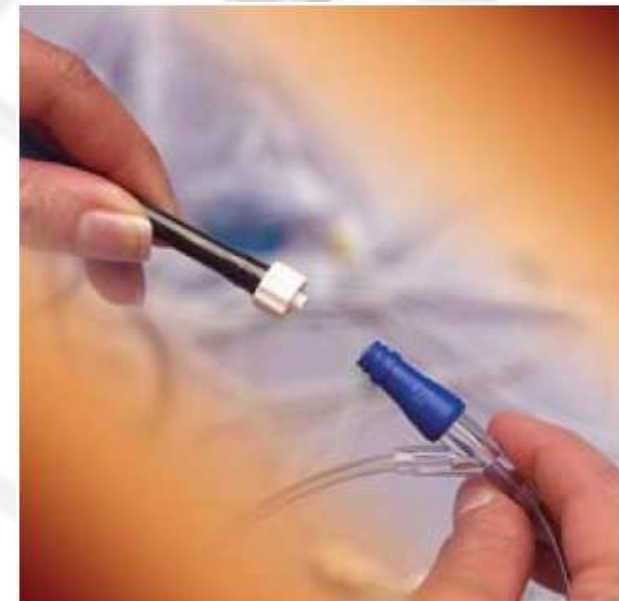
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Misconnection of Blood Pressure Monitors to IV Lines

- ▶ Common Luer fittings makes this an easy mistake
- ▶ Not common but results can easily be fatal
- ▶ Results in large volume of air being pumped into patient's vasculature
- ▶ Remove NIBP monitors with Luer connectors
- ▶ Look for other misconnection problems



Infusion Pumps – A Real-World Application



Infusion Pump Programming Errors

- ▶ IV pumps used throughout hospital often delivering very potent medications
- ▶ Errors are easy to make and are often fatal
- ▶ Solutions include dose error reduction systems (DERS) and set-based free-flow protection
- ▶ DERS can be effective but require major time commitments to adopt



Hazard and Recall Story

post-gazette.com

Health, Science & Environment

Pittsburgh, Pa.
Monday, June 20, 2005

Health & Science
Previous Articles
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Health

Monroeville hospital urges 200 colonoscopy patients to get checked for hepatitis, HIV

Colon test infection fears

Thursday, March 31, 2005

By Joe Fahy and Byron Spice, Pittsburgh Post-Gazette

Officials at [Forbes Regional Hospital](#) in Monroeville are warning about 200 patients who underwent colon examinations that they may be at risk for infection because the colonoscopes used had not been adequately cleaned.

The risk of infection is extremely low, hospital officials and local and national health authorities said. But certain patients who had colonoscopies at Forbes between Oct. 28 and Feb. 26 nevertheless are being advised to have their

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A summary of reported problems, hazards, recalls, and updates

Action Items
February 28, 2003
Vol. 27, No. A9

FRESENIUS — MODEL 2008H HEMODIALYSIS UNITS: INADEQUATE WIRING
Hemodialysis Units [11-218]
Device: Model 2008H Hemodialysis Units
Manufacturer: Fresenius Medical Care North America [312187], 95 Hayden Ave, Lexington MA 02420-9192
Problem: An ECRI member hospital reported overheating and device failure of the above hemodialysis units. On investigation, the hospital determined that the most likely cause of the problem was inadequacy of the crimp connections. The manufacturer acknowledged receiving other reports of the problem but offered no solution. ECRI agrees with the hospital that the cause was poor crimp quality but does not believe that this problem presents a safety hazard to the patient or the hospital.
Action Needed: (Note: Refer to the original report, cited below, for the rationale behind the following recommendations.) ECRI recommends that biomedical engineering staff be aware of the issue and do the following: (1) Check for early signs of the problem, such as discolored or deformed insulator jackets in or near the power supplies. (2) Check the power supplies in all Model 2008H units for signs of overheating. If such signs are present, remove the damaged wiring and replace the crimp connector. For further information, see the original report.

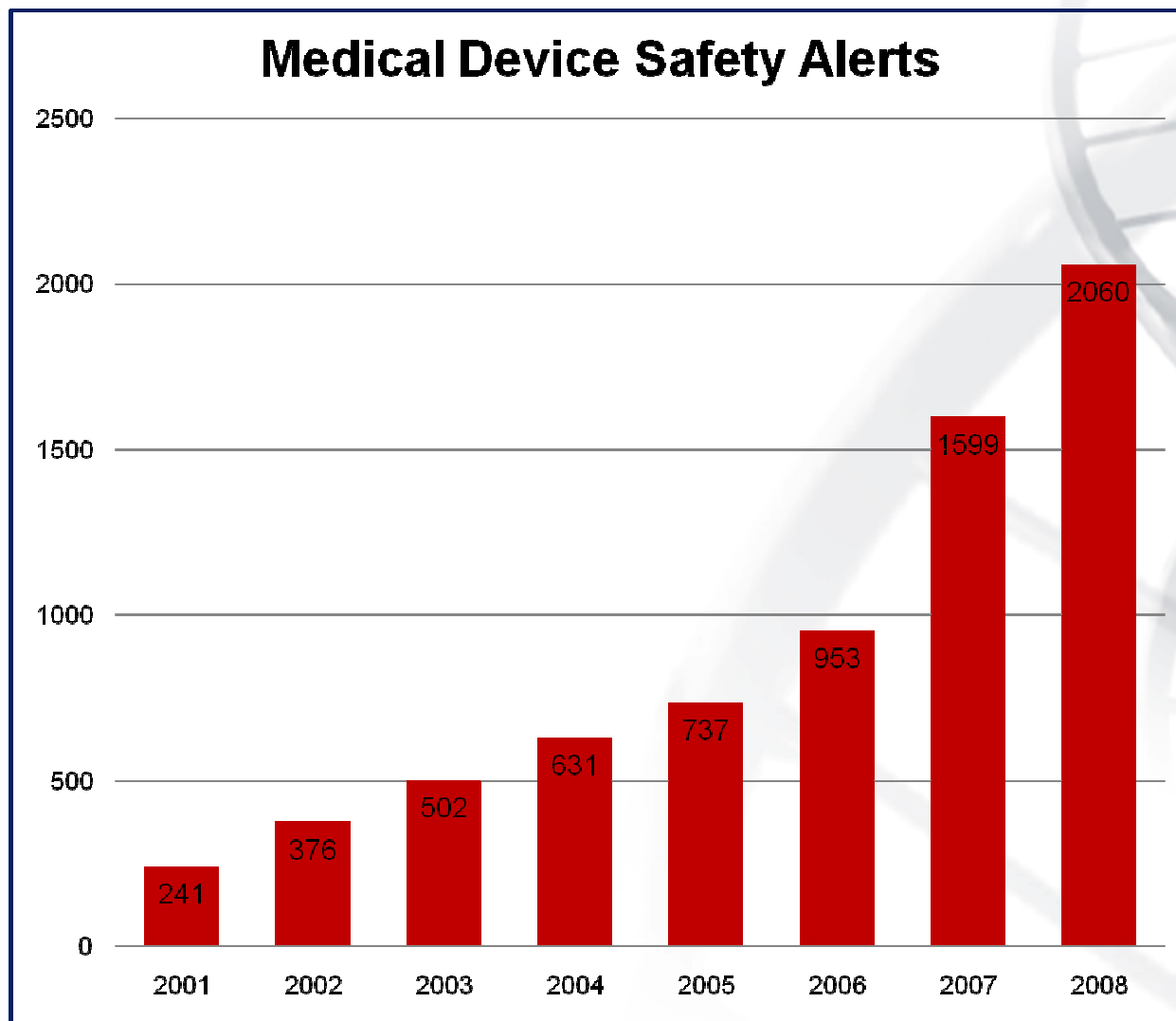
Comment: ECRI recommends that this Action Item be distributed to the following departments: CCU/ICU/NICU, dialysis/nephrology, endocrinology, and home care. Additionally, you should determine if other departments, locations, or individuals at your facility should receive this report.
Accession No.: A4989
☐ None Present: ☐ Action Taken: _____

OLYMPUS — EXERA GASTROINTESTINAL ENDOSCOPES WITH AUXILIARY WATER CHANNELS: REMINDER TO REPROCESS WATER CHANNEL
Gastrosopes [11-856]
Device: EXERA Gastrointestinal Endoscopes: (1) Model CF-Q160AI, (2) Model CF-Q160AL, (3) Model CF-Q160I, (4) Model CF-Q160L, (5) Model CF-Q160S, (6) Model GIF-2T160
Identifier: Units distributed in the U.S. and internationally
Manufacturer: Olympus America Inc Endoscopy Group [364575], Two Corporate Center Dr, Melville NY 11747-3157
Problem: Olympus has received reports that users may inadvertently be neglecting to reprocess the auxiliary water channel found on the above endoscopes. The auxiliary water channel allows the

February 28, 2003 – Two Years Earlier!

Same Problem

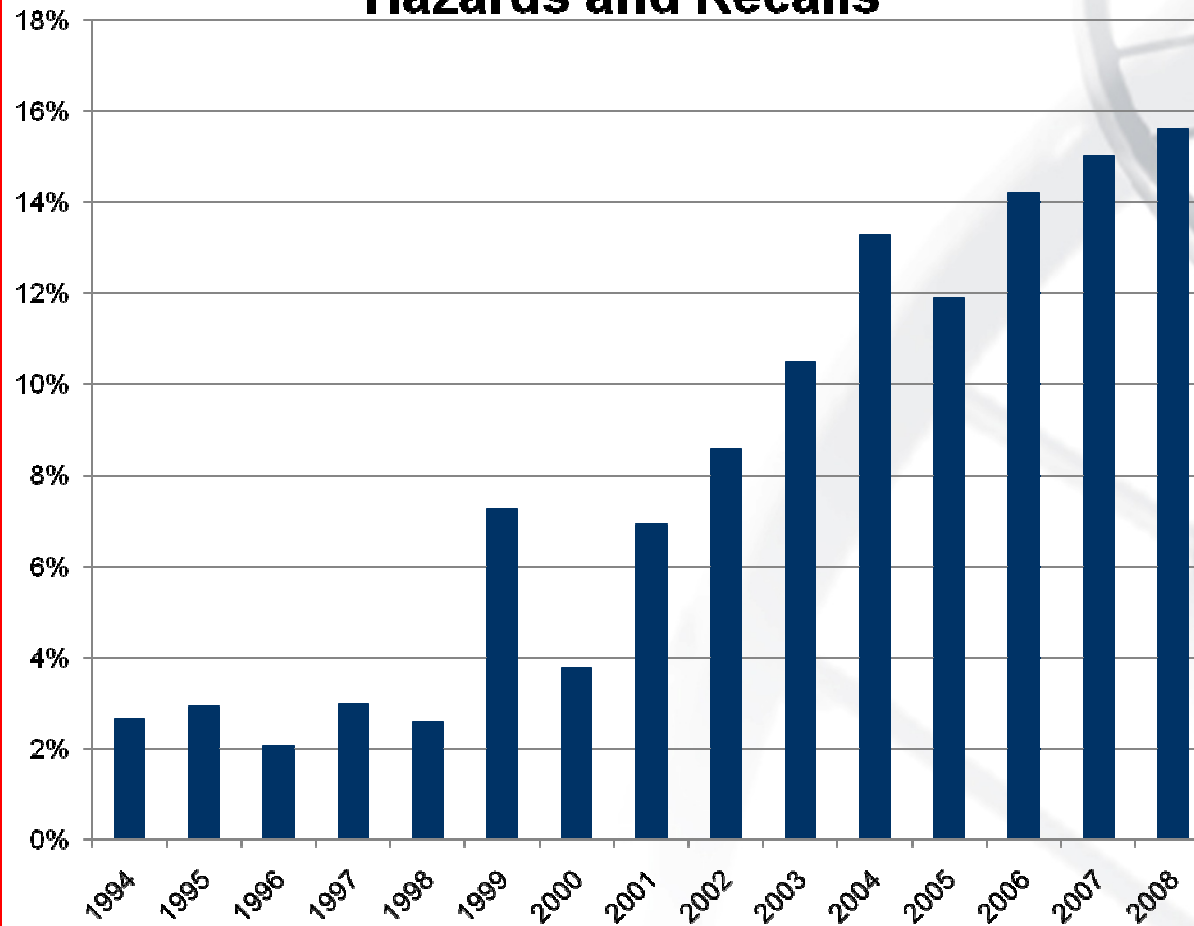
Medical Device Safety Alerts



Hazard and Recall Management

- ▶ As part of ECRI's mission to improve patient safety, since 1977 we have published Health Devices Alerts to inform healthcare professionals about medical device hazards and recalls
- ▶ ECRI has published over 50,000 Health Devices Alerts Action Items and Abstracts since then
- ▶ In 2003 ECRI introduced its "Alerts Tracker" service to facilitate the electronic distribution and tracking of its notices

Percentage of Software-Related Hazards and Recalls



Information Technology – A New Safety Concern

Source: ECRI Institute, Data-Transfer Problems between Imaging Devices and PACS Could Result in Misdiagnosis. *Health Devices* [Hazard Report]. December 2008;37(12):381-3.



1. When zoomed computed radiography images were exported to a PACS, measurements made by the PACS were inaccurate (Accession Nos. A9718 and A11161).
2. A PACS software error caused inaccurate processing of data from a cardiac ultrasound scanner, resulting in inaccurate display of heart wall motion abnormality scores (Accession No. A10368).
3. Reconstructed images generated by a PACS were incorrectly oriented when patients were not scanned supine and head first (Accession Nos. A10156 and A11115).
4. An anomaly between a PACS and modality caused patient data to be overwritten or matched to an incorrect patient (Accession No. A9812).
5. Sections of images from breast studies obtained by certain modalities were not displayed on a PACS (Accession No. A8325).

Converging Technology – Other Safety Concerns

- ▶ “Interoperability” or lack thereof
- ▶ Wireless “dead zones”
- ▶ Information overload
- ▶ Information loss, security breaches, and malware
- ▶ Growing number and complexity of recalls
- ▶ Lack of understanding about mission- vs. life-critical issues

Medical Technology Safety Survey

- ▶ Routine assessment of how you are doing
- ▶ Focus on technologies with a high-level of concern (e.g., among the Top Ten)
- ▶ Establish a checklist for regular (e.g., annual) walk-through
- ▶ Examples
 - Infusion pump set-based free-flow protection
 - Observation of clinical alarm settings
 - Misconnection possibilities
 - Follow-through on known hazards and recalls

General Recommendations

- ▶ Pay close attention to appropriate technology selection and use
- ▶ Establish safety-related device selection criteria
- ▶ Plan for user training during technology acquisitions
- ▶ Conduct ongoing training and check for proficiency
- ▶ Plan for new technology at the right time and for the right reasons
- ▶ Monitor for ongoing risks, take appropriate steps to reduce risk, and document actions taken

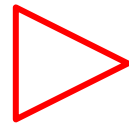
Keep an Eye out for the Next Top Ten Health Technology Hazard List from ECRI Institute

Top Candidate – endoscope reprocessing-related infections



Useful References

- ▶ Top 10 Health Technology Hazards. *Health Devices*, November 2008
- ▶ Top 10 Health Technology Hazards - Are You Protecting Your Patients from These High-Priority Risks? - *Health Devices*, November 2007
- ▶ www.ecri.org



Thank
You