



Medical Technology and Patient Safety

New York State Department of Health
Patient Safety Conference

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Vice President
Health Technology Evaluation and Safety*

May 21, 2007



Re-Introducing

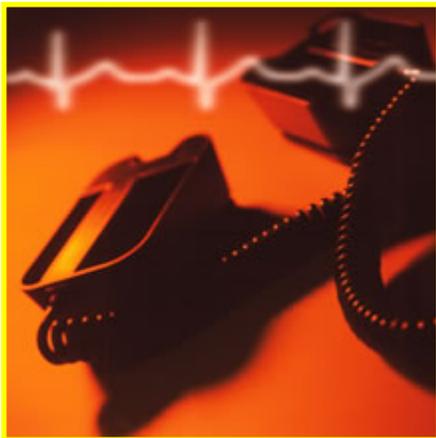
▶ **ECRI** Institute

The Discipline of Science. The Integrity of Independence.

Company Overview

Who is ECRI Institute?

- ▶ ECRI Institute is a nonprofit healthcare research organization
- ▶ Our mission is to enable our members to improve patient care
- ▶ For 40 years we have dedicated ourselves to applied scientific research to discover which technologies and patient care approaches are best



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Health Devices Journal

HEALTH DEVICES

March 2007, Volume 36, Number 3

Guidance Article

The Hazards of Alarm Overload

Keeping Excessive Physiologic Monitoring
Alarms from Impeding Care



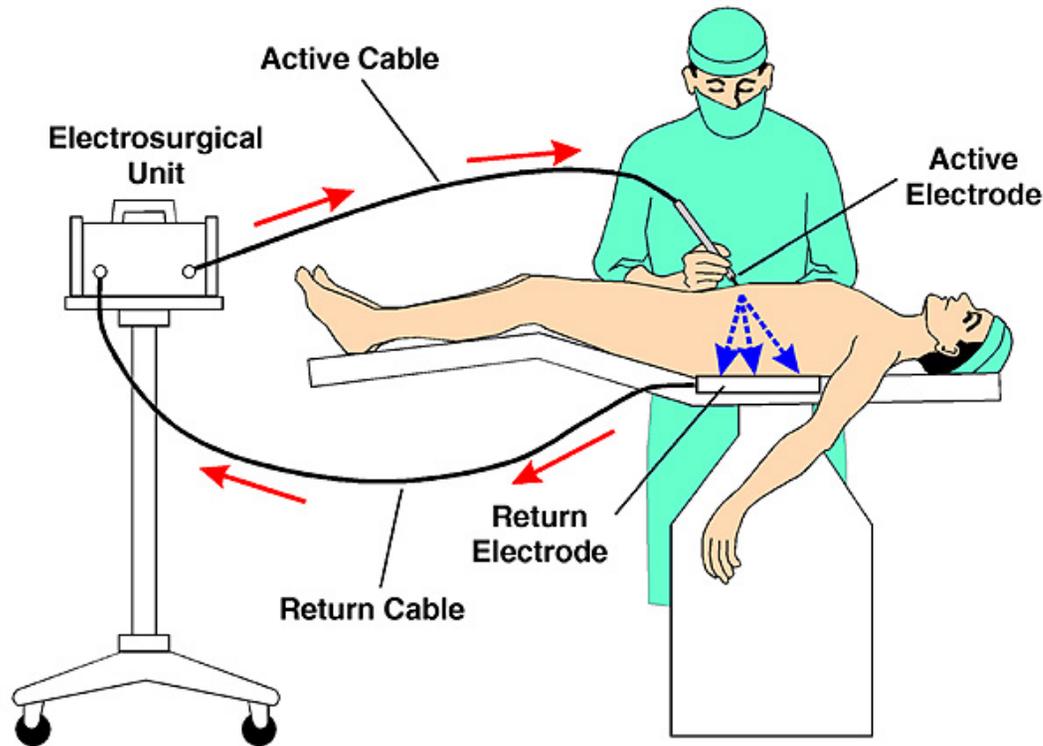
Typical guidance
article on patient
safety

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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

Common Problem – Close to Home



User Error

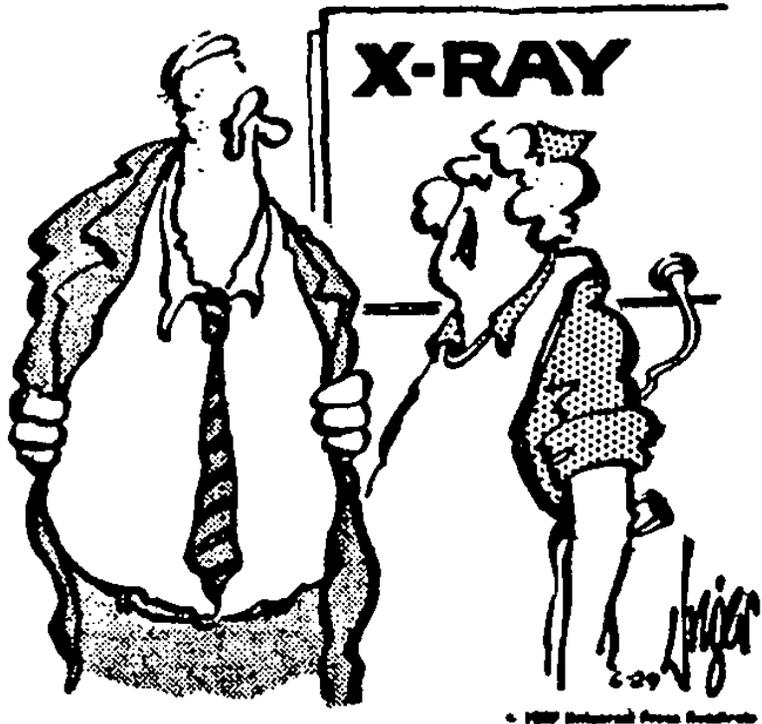
50 - 70% of Device Accidents

- ▶ Pre-use inspections
- ▶ Labeling
- ▶ Misassembly
- ▶ Misconnection
- ▶ Improper (“bad”) connection
- ▶ Incorrect clinical use
- ▶ Incorrect control settings
- ▶ Incorrect programming
- ▶ Spills
- ▶ Abuse
- ▶ Inappropriate reliance on automated features
- ▶ Failure to monitor
- ▶ Maintenance or incoming inspection
- ▶ Failure to follow or have preventive procedures

Tuesday, June 29, 1982

Philadelphia Inquirer

Herman



"Don't bother undressing. I'll turn up the power."

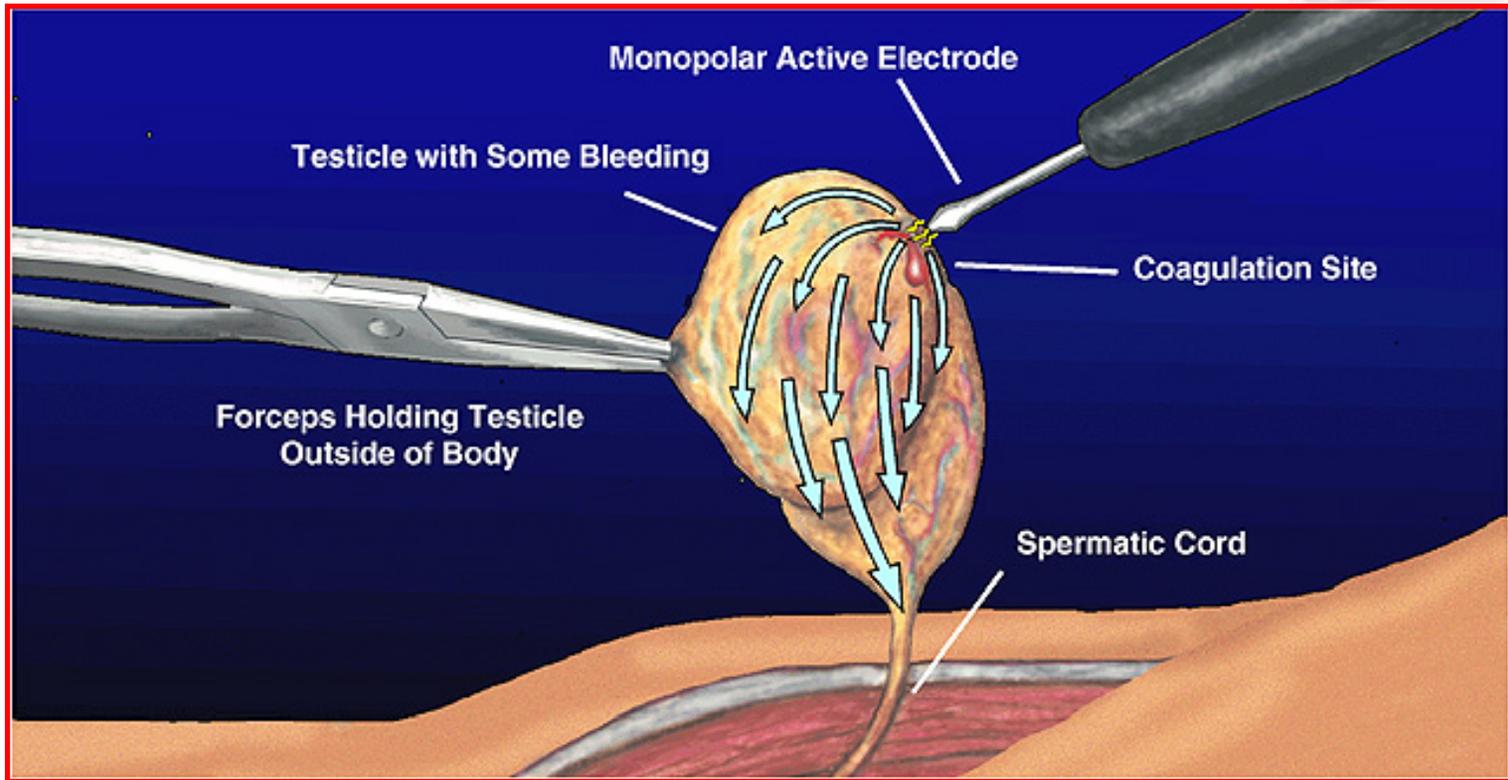
Is This
User
Qualified?

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Key Concerns - “Top Ten List”

- ▶ Infusion technology
- ▶ Ventilators and anesthesia systems
- ▶ Patient monitors
- ▶ Defibrillators
- ▶ Cutting and coagulating surgical devices (e.g., electro-surgical units)
- ▶ Heart-lung bypass and circulatory assist devices
- ▶ Catheters and needlestick prevention devices
- ▶ Trocars and staplers
- ▶ Reprocessing of endoscopy instruments
- ▶ Magnetic resonance imaging

A Scary User-Related Problem



Spermatic Cord Damage from Electrosurgery



Chicago Tribune

Chicagoland
South
50¢ newsstand

Monday, September 11, 2000

INVESTIGATIVE REPORT

dangerous care: nurses' hidden role in medical error

Nursing accidents unleash silent killer



Tribune photo by Stephanie Sinclair

Nurse Edith Julian-Stiegel programs one of seven infusion pumps hooked up to a patient at the University of Chicago Hospitals. The hospital has banned pumps lacking protection against an uncontrolled surge of medicine into the body.

A Serious
and
High-Profile
Problem

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An Accident Waiting to Happen!



Dose Error Reduction Systems

- ▶ New technology in 2002
- ▶ Establishes limits on setting flow rates for infusion pumps
- ▶ Significantly reduces risk from overdose
- ▶ In 2002 ECRI rated products without dose error reduction as Not-Recommended
- ▶ At the end of 2006 all major infusion and PCA pump vendors offered products with dose error reduction features

Management of Hazards and Recalls

post-gazette.com[®] **Health, Science & Environment**

Pittsburgh, Pa.
Monday, June 20, 2005

Health & Science
Previous Articles
Health
Science
Environment

Health

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

Colon test infection fears

March 31, 2005

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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This Issue Has Been Covered Before

HEALTH DEVICES ALERTS™ 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
Gastroscopes [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

Best Practices for Management of Hazards and Recalls

- ▶ Clearly defined roles and responsibilities
- ▶ Consistent naming conventions for devices and systems
- ▶ Approved and comprehensive sources for information
- ▶ Reliable and consistent dissemination of information
- ▶ Accountability and follow-through

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 regular ongoing training and check for proficiency
- ▶ Plan for new technology at the right time and for the right reasons



▶ Thank you
Questions?