An Interdisciplinary Forensic Approach to Solving Medical Device Cases

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- Senior Biomedical Engineer
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- Research Specialist
- Financial Assistant
- Administrative Assistants
Where to Begin

- Define medical technologies involved using:
  - FDA nomenclature and classification database
  - ECRI device classification (Sourcebase) database
Medical Literature Search

- Locate background medical literature regarding specific condition, procedure, etc.
- Locate articles pertaining to device usage
- Locate news-related information regarding device and/or manufacturer (if relevant)
  - Attorney webpages devoted to specific recalls
  - Biomed listserv
Medical Literature Search

- PubMed
- WorldCat
- Google Scholar
- Netlibrary
- ECRI search
Device-Related Information Search

- FDA MAUDE database
- FDA 510(k) or PMA Paperwork
- FDA Device recalls, “Dear Doctor” letters
- Patent Office database
- Device manuals (user, physician, technical)
Engineering Website Search

- Standards and other engineering material
  - ILI Standards Infobase
  - AAMI
  - ANSI
  - ASTM
  - ISO
  - IEEE
  - ECRI
    - Health Devices database
    - Sourcebase database
Case-Related Document Search

- Medical Records
- Manufacturer Complaint File
- Deposition transcripts
Inspection and/or Testing

- Inspection of facility
- Exemplar device simulation
- Subject device testing
Closed Case Examples

- Operating room fire
- Patient lift injury
- Heart catheter burn
- Dialysis water treatment system
Operating Room Fire

- Serious debilitating burns
- Major lawsuit against hospital and surgeon
O.R. Fire Background

- Patient was undergoing excisional biopsy of left cervical lymph node
- Nurse anesthetist utilized conscious sedation on patient
- Supplemental oxygen was provided via nasal cannula and mask (10 liters/min. presurgery; 2 during surgery)
- Surgeon used an ESU
- Flash fire occurred, burning patient’s face
O.R. Fire Literature Search

- PubMed
- Google Scholar
- ECRI
To get started with PubMed, enter one or more search terms.

Search terms may be topics, authors or journals.
((electrocautery OR electrosurgery OR esu) AND fire AND anesthesia AND oxygen AND operating room)
Items 1 - 12 of 12

1: Goldberg J.
   Brief laboratory report: surgical drape flammability.
   PMID: 17048554 [PubMed - indexed for MEDLINE]

2: Kaddoum RN, Chidiac EJ, Zestos MM, Ahmed Z.
   Electrocautery-induced fire during adenotonsillectomy: report of two cases.
   PMID: 16563331 [PubMed - indexed for MEDLINE]

   Injury and liability associated with monitored anesthesia care: a closed claims analysis.
   Anesthesiology. 2006 Feb;104(2):223-34.
   PMID: 16436839 [PubMed - indexed for MEDLINE]

4: Paugh DH, White KW.
   Fire in the operating room during tracheotomy: a case report.
   PMID: 15835828 [PubMed - indexed for MEDLINE]

5: Singla AK, Campagna JA, Wright CD, Sandberg WS.
   Surgical field fire during a repair of bronchoesophageal fistula.
   PMID: 15781523 [PubMed - indexed for MEDLINE]

6: Weaver JM.
   Fire hazards with ambulatory anesthesia in the dental office.
   PMID: 15366316 [PubMed - indexed for MEDLINE]
Surgical Field Fire During a Repair of Bronchoesophageal Fistula

Aneesh K. Singla, MD, MPH*, Jason A. Campagna, MD, PhD*, Cameron D. Wright, MD†, and Warren S. Sandberg, MD, PhD*

Departments of *Anesthesia and Critical Care, and †Surgery, Massachusetts General Hospital, Harvard Medical School, Boston, Massachusetts

Most surgical fires involve the airway but they can also occur in the surgical field. Herein, we report an intraoperative fire in the surgical field during repair of a bronchoesophageal fistula. During the portion of the surgery after the fistula was divided and the bronchus was open to atmosphere, continuous positive airway pressure was applied to the nondependent lung, and in conjunction with the use of electrocautery and dry sponges in the field, resulted in a fire. Anesthesia for thoracic surgery carries unique risks of fire because these patients frequently require large oxygen concentrations, special interventions for improving oxygenation, and have variable degrees of airway disruption. This report highlights unique safety concerns during anesthesia for thoracic surgery, and addresses more general safety issues relating to fire risk in all surgical patients.

(Anesth Analg 2005;100:1062–4)

Operating room fires, though rare, can involve substantial morbidity and mortality. The most commonly reported surgical fires occur during laryngeal, pharyngeal, tracheostomy, and bronchoscopy procedures. The majority of these fires occur in the airway (34%) and head and neck area (28%) and only a small fraction (14%) occur in the patient (1). Surgical fires require an ignition source, and oxidizer and fuel, provided generally by surgeons, anesthesia providers, and nurses, respectively. Ignition sources generally include (but are not limited to) lasers and electrocautery, oxidizers are usually oxygen, nitrous oxide, and ambient air, whereas fuels are classically

Case Report

A 74-yr-old man was transferred to our hospital after an Ivor-Lewis esophagectomy for Barrett’s adenocarcinoma of the esophagus. The surgical procedure for the treatment of esophageal cancer occurs in two stages. An abdominal incision is made first and if there is no evidence of metastatic disease, the stomach and distal esophagus are dissected free and the incision is closed in a standard manner. The patient is then repositioned in a left lateral decubitus position and a right thoracotomy incision is made. Through this incision, the diseased region of the esophagus is resected, an esophageal anastomosis is made, and the stomach and remaining esophagus is “pulled” into the mediastinum. The procedure requires lung isolation to facilitate surgical access to the
Operating room fire
Cited by 8 - Related articles - Web Search - All 2 versions

Operating Room Fires Initiated by Hot Wire Cautery. Case Report
EH Axelrod, ABMD Kusnetz, MKMD Rosenberg - Anesthesiology, 1993 - anesthesiology.org
Cited by 12 - Related articles - Web Search - BL Direct - All 3 versions

CME Fire in the Operating Room: Principles and Prevention. - prsjournal.org [HTML]
SP Daane, BA Toth - Plastic and Reconstructive Surgery, 2005 - plasreconsurg.com
... Lists of fire prevention techniques and steps to take in the event of an operating room fire are provided. ... Operating Room Fire Safety Guidelines TOP. ...
Cited by 5 - Related articles - Web Search - All 4 versions

Fires in the Operating Room and Intensive Care Unit: Awareness is the Key to Prevention - anesthesianet....
Fires in the Operating Room and Intensive Care Unit: Awareness is the Key to Prevention

Rajnish Prasad, MD, Zenaide Quezado, MD, Arthur St. Andre, MD, and Naomi P. O'Grady, MD

Critical Care Medicine Department, National Institutes of Health, Bethesda, Maryland

Recent recommendations from the Centers for Disease Control (CDC) to use alcohol-based substances for hand hygiene and skin antisepsis could introduce new fire hazards in the operating room (OR) (1). This potential for an increase in the number of fires in the hospital setting with wide spread use of alcohol-based agents warrants heightened awareness of the risks and implementation of safety measures when using these agents. Here, we report a patient who, during a tracheostomy, sustained severe burns resulting from a fire in the OR. In this case, the use of an alcohol-based antiseptic was the major contributing factor to the surgical fire.

(Anesth Analg 2006;102:172–4)
Operating room fire

There are approximately 280 results, shown below. (Show 10 results per page.)

Too many results? Use the categories at left to narrow your results.
Additional results may be available in products to which you do not currently subscribe.
Would you like to see those results and learn more about ECRI Institute's additional subscription products?

Page 1 of about 28 pages
1 2 3 4 5 6 7 8 9 10 >>

Relevance Document Name

64.6% Selecting Fire Extinguishers for the Operating Room
Selecting Fire Extinguishers for the Operating Room ... What type of fire extinguisher should we have in our operating rooms (ORs) ... Selecting Fire Extinguishers for the Operating Room
47 KB

... Allegedly, in an operating room flash fire incident, a spark from an electrosurgical device being u ... Infant dies after operating room flash fire. ... Infant dies after operating room flash fire.
5 KB

83.5% McCranie J. Fire safety in the operating room. Todays OR Nurse
Jan-Feb;16(1):33-7.
... author discusses operating room (OR) fires and states that members of the surgical team must be vig ... 25209 Operating Room Equipment ab 04/15/94 McCranie J. Fire safety in the operating room. ... McCranie J. Fire safety in the operating room.
5 KB
A Clinician’s Guide to Surgical Fires
How They Occur, How to Prevent Them, How to Put Them Out
O.R. Fire Literature Search - News

Related

- 20/20 Fire in the OR
### Search for FDA-Related Material

#### Search MAUDE Database

Enter one or a combination of the MAUDE Search Values and select Search.

<table>
<thead>
<tr>
<th>Field</th>
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For full-text search, select Go To Simple Search button.

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### Advanced Search Option

Go to Simple Search  10  Records per Report Page  Search  Clear
Search for FDA-Related Material

Boolean searching possible, but restrict to specific year(s)

Search MAUDE Database

Enter a search term below, choose a date range and select Search

fire AND oxygen AND bovie

Enter a single word (e.g., electromechanical), an exact phrase (e.g., electromechanical pump) or multiple words. To search by Brand Name, Manufacturer, Event Type, 510K Number, PMA Number, Product Code, or date, select Go To Advanced Search button.

Date Report Received by FDA

2008
2007
2006
2005

(press CTRL key for multiple years)

Go to Advanced Search 10 Records per Report Page Search Clear

Simple Search Option
Adverse Event Report

ELECTROSURGICAL UNIT

Catalog Number
Event Date 12/11/2006
Event Type Malfunction
Event Description
Reportedly, there was a device related fire in the operating room. The patient sustained 2nd degree burn and silvadine was used for treatment. Bovie was used with oxygen which ignited during a temporal biopsy. The patient had one procedure done earlier and was about to receive the 2nd surgery. The generator was at 30/30 setting. There was no report of additional patient injury.

Search Alerts/Recalls
Adverse Event Report

BIPOLAR CORD BIPOLAR CABLE/CORD

Catalog Number

Device Problem Spark

Event Date 06/11/2007

Event Type Injury Patient Outcome Required Intervention

Manufacturer Narrative

The manufacturer was not able to obtain any further info concerning the reported event or retrieve the "suspect" cable for analysis from the end-user. This is the first report of such an occurrence for this reported "suspect" cable out of five million distributed in the past five years. Cables manufactured are tested and inspected to applicable international performance standards prior to shipment. **This cable is a single-use disposable low frequency bipolar type and it is unlikely that a cable of this nature would spark when used correctly.** The manufacturer will continue to attempt in obtaining further info from the user site so a comprehensive investigation and root cause analysis may be performed. The manufacturer is presently evaluating and testing cables that are identical as the one used during the reported event. A follow-up report will be provided to the agency when new info is made available.

Event Description

It was reported that during an electro-surgical procedure in the operating room, the drape covering the pt caught on fire and subsequently received a burn. The reporter "suspected" that the bipolar cord sparked and ignited the drape during the procedure. There was no info provided detailing the procedure, pt sex, age, degree of the burn sustained and the treatment after the burn, electrosurgical unit and bipolar components used during the reported event.
Instructions for Use

**Warning**

*Fire Hazard:* Electrosurgical accessories that are activated or hot from use can cause a fire. Do not place them near or in contact with flammable materials (such as gauze or surgical drapes). Use a holster to hold electrosurgical pencils and similar accessories safely away from patients, personnel, and surgical drapes.

- Handswitching pencils - activate by pressing either the handswitch cut or coag button.

- Monopolar handswitching forceps (for coagulation only) - activate by closing the forceps tines.

- Bipolar handswitching forceps (for coagulation only) - activate by closing the forceps tines.

- Monopolar footswitching accessories (e.g., endoscopes, forceps, or chuck handles) - activate by pressing the appropriate pedal on the monopolar footswitch.

- Bipolar footswitching forceps - activate by pressing the bipolar footswitch pedal or activate by pressing either monopolar footswitch pedal with the front panel footswitch selector in the bipolar mode.

**Caution**

Do not activate the generator until the forceps have made contact with the patient. Product damage may occur.
Fire/Explosion

Danger: Explosion Hazard: Do not use in the presence of flammable anesthetics.

Warning: Fire/Explosion Hazard: The following substances will contribute to increased fire and explosion hazards in the operating room:

- flammable substances (such as alcohol based skin prepping agents and tinctures)
- naturally occurring flammable gases which may accumulate in body cavities such as the bowel
- oxygen enriched atmospheres
- oxidizing agents (such as nitrous oxide [N₂O] atmospheres).

The sparking and heating associated with electrosurgery can provide an ignition source. Observe fire precautions at all times. When using electrosurgery in the same room with any of these substances or gases, prevent their accumulation or pooling under surgical drapes, or within the area where electrosurgery is performed.

Fire Hazard with Oxygen Circuit Connections

Warning: Fire/Explosion Hazard: Verify that all oxygen circuit connections are leak free before and during the use of electrosurgery. Verify that endotracheal tubes are leak free, and that the cuff is properly sealed to prevent oxygen leaks. Enriched oxygen atmospheres may result in fires and burns to patients or surgical personnel.
Utilize exemplar device model(s) to assist in determining failure mode, guided by:

- Field Notes from ECRI
- Experienced clinical consultants familiar with head and neck surgery:
  - OR Nurse
  - CRNA
- Testimony:
  - CRNA
  - Surgeon
  - OR Staff
Towels with Towel Clamps
Fenestration Cuts

Surgeon made cuts (arrows) to place the laparotomy drape. The double stick tape remained intact.
Slight Mask Displacement

Slight displacement allows respiratory gas to escape from the bottom of the mask at the jaw line.
CRNA Showing Hand on Mask - Note: Slight movement of mask allows exhaled gas to vent toward surgical site.
Arrow indicates path for exhaled gas from mask to surgical site.
Dräger Monitor Sample Line Placement

Tip of Gas Sample Line
Patient Movement

• Immediately before fire, patient was moving and required restraint

• Movement created increased oxygen in wound site
  • Deeper breaths taken by patient when stimulated
  • CRNA removed his hand from the mask prior to fire, increasing gap between mask and face
  • Movement of patient and drapes forced an accumulation of trapped oxygen at wound site
Waveforms at Surgical Site
after Patient Movement

Oxygen concentration noted at 47%
Oxygen enters top of chamber via metal tube, passes through chamber and vents out bottom holes. ESU electrode touches a piece of fat adjacent to a piece of cloth surgical towel on metal stand. Oxygen level is simultaneously monitored by in-line oxygen monitor (pictured) and the Dräger Monitor (not pictured).
ESU electrode on the fat near cloth towel. ESU activated at 40 COAG on the fat.
Biomedical Engineering Analysis of Adverse Outcome

- Enhanced oxygen concentration
- Physical arrangement of one-way oxygen & drapes
- Heat from ESU activation
FIRE TRIANGLE

Spark from ESU

- HEAT
- OXYGENATION
- FUEL

Expired O₂

- Fat and tissue particles
- Towels and drapes
- Face mask, bag and tubes
- Patient
Recommendations

- Stop oxygen for 1 minute before ESU activation; or
- Use incise drape to make a stable, gas impermeable barrier around surgical site; or
- Use non-thermal means to cut and coagulate tissue; or
- Use an anesthesia circle system to keep oxygen isolated
Patient lift injury

- Injury caused by worn part
- Potential lawsuit from family members
Three staff members moved patient from bed to geri-chair using subject lift. Base legs of subject lift were placed under chair then moved to open position by locking shifter handle into mounting slot. Patient was then lowered into geri-chair.
As sling straps were unhooked from hanger bracket, lift tilted sideways (toward back of geri-chair)

Hanger bracket struck staff member’s face, then hit patient’s forehead

One base leg of subject lift came off ground and began raising geri-chair

Second staff member struck in groin while attempting to keep geri-chair from tipping backward
Research Results

- PubMed Results
- Google Scholar
- FDA MAUDE Database
Operator’s Manual for Patient Lift

**WARNING**
The operation of the patient lift is an easy and safe procedure. DO NOT attempt any transfer without approval of the patient’s physician, nurse or medical assistant. Thoroughly read the instructions in this Owner’s Manual, observe a trained team of experts performing the lifting procedures and then perform the entire lift procedure several times with proper supervision and a capable individual acting as a patient.

**ONLY** operate this lift with the legs in **MAXIMUM OPEN POSITION** and **LOCKED** in place. The base legs MUST be locked in the open position at all times for stability and patient safety when lifting and transferring a patient.

**WARNING**
If the shifter handle is **NOT** positioned completely into its mounting slot, **DO NOT** use the patient lift until shifter handle is properly seated and the legs of the patient lift **LOCKED** in place or injury and/or damage may occur.
Lowering Patient onto Geri-Chair
Patient on Geri-Chair Prior to Strap Removal
Position of Staff Member Foot While Unfastening Lift Straps
Force Gauge Used to Test Subject Lift
Findings

- Lift became unstable when shifter handle disengaged from open to closed position.
- Force required to move legs from open to closed position was approximately 14 lbs.
- Newer lift would not move from open to closed position with over 60 lbs force.
Findings, cont.

- Inspection of base plate showed wear of cross support tab

- Comparison with new lift indicated design change of mount handle from grooved to solid
Detailed View of Mount Handle

Machined groove on part number 20.

Cross support tab exhibiting rounded edges & containing metal filings.
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<th>Item</th>
<th>Part / Kit</th>
<th>Part / Kit Description</th>
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</table>

**Low Base Shown**
Adverse Event Report

Model Number

Device Problems Design/structure problem; Device tipover; Locking mechanism failure

Event Date 12/22/2005

Patient Outcome Required Intervention;

Event Description
The incident occurred just after a resident had been lowered into a geri-chair, and while still in the sling. The base logs had been locked out prior to the pt being lowered. As two staff members were unhooking the sling straps from the hanger bracket, the lift tilted sideways. The hanger bracket struck a staff member in the lip and chin, and then hit the resident in the forehead. As the lift was tilting sideways, one of the logs (both of which had been positioned under the geri-chair prior to the resident being lowered into it) caused the geri-chair to rise up. Before it could be repositioned back onto the floor, it struck another staff member in the groin. The resident sustained a non-displaced nasal fracture and required twenty-five stitches to close the forehead laceration.
Model Number

Event Date 12/22/2005

Event Type Injury  Patient Outcome Required Intervention;

Event Description
While the resident was being transferred from the bed to a geri chair, the lift allegedly tipped. The hanger allegedly hit the resident in the head resulting in a cut to the forehead requiring 25 stitches and a broken nose.

Manufacturer Narrative
Manufacturer spoke with the facility. The lift has been in use since 2001. During a transfer of a pt the lift inadvertently tipped. No allegation of defect with product. As a precaution inspection is pending. Current user guide covers proper transfer methods and use.

Manufacturer Narrative
Photos of the alleged device were received and reviewed. A photo of complete device indicates the device is functional. However, a single photo of the shifter handle assembly demonstrates the device is in need of maintenance. No history to suggests a product problem. Current user guide covers this area. Manufacturer views this incident as a lack of maintenance.
Updated FDA MAUDE Search

Adverse Event Report

Model Number [redacted]
Event Date 04/01/2008
Event Type Injury Patient Outcome Required Intervention;
Manufacturer Narrative
Device has been in use for 8 years and is no longer in warranty, info indicates a potential transfer error. Unclear if proper maintenance has been performed on the lift prior to alleged incident. Mdr filed based on serious injury claim.

Event Description
The manual base widening mechanism allegedly closed the legs during the transfer, causing the lift to turn on it's side and the consumer to fall onto the tile floor. The consumer allegedly sustained a hip fracture.
Heart catheter burn

- Injury caused by software-related problem
- Major lawsuit against manufacturer

Thermodilution catheters help you determine hemodynamic pressures and cardiac output rapidly when used with a compatible cardiac output computer. They are available with multiple tip configurations, infusion lumens and stiffness characteristics to accommodate use in the OR, ICU and Cath Lab.
Patient was treated for coronary artery bypass graft surgery.

During surgery, patient was monitored by the Vigilance I monitor with associated cable & catheter.

During patient surgery, error code on the monitor instructed switch from CCO to bolus modes.
Incident Background, cont.

- Software error caused monitor to deliver 20 watts to thermistor instead of 1-2 watts
- Because of bypass surgery, lack of blood flow precluded cooling from occurring
- Anesthesiologist assumed monitor was in stand-by mode
- Following bypass, surgeon was unable to pull out the catheter, stating "...end of it had just carbonized where it was just cooked."
Monitor
**CCO Catheter Modifications**

**Balloon Inflation Volume**
- Appropriate inflation volume is 1.25 – 1.5 cc

**VIP Port**
- 30 cm from tip
- Located in RA/SVC

**Proximal Injectate Port**
- 26 cm from tip
- Located in RA
- Transduce Proximal Injectate Lumen – proper waveform is RA

**PA Distal Port**
- Transduce distal lumen – proper waveform is PA

**Thermistor**
- 4 cm from tip

**Pulmonic Valve**

**Tricuspid Valve**

**Thermal Filament**
- 14 – 25 cm from tip
- Rests between RA and RV
- Should be free floating and avoid endocardial surface
- Should not be in PA
Description of Continuous Cardiac Output & Bolus Modes

The Monitor measures cardiac output continuously by introducing small pulses of energy into the blood and recording blood temperature via a pulmonary artery catheter. Cardiac output is computed using a conservation of heat equation, and indicator dilution curves are obtained by cross-correlation of the energy input and blood temperature waveforms. After initialization, the monitor continuously displays the patient’s cardiac output without the need for user calibration or intervention.

To measure cardiac output intermittently using the bolus thermodilution technique, a small amount of indicator of a known volume and temperature is injected through the catheter injectate port, and the resultant decrease in blood temperature is measured by the thermistor in the Pulmonary Artery (PA). The Monitor plots a curve representing the decrease in blood temperature over time and integrates the data based on the Stewart-Hamilton indicator dilution equation. The area beneath the thermodilution curve is calculated and displayed in numeric form (in liters per minute).
<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>1993</td>
<td>Vigilance monitoring system put on market, Chief Competitor: Abbott/Hospira</td>
</tr>
<tr>
<td>1998</td>
<td>Software &quot;bug&quot; discovered</td>
</tr>
<tr>
<td>1999</td>
<td>Software “bug” fix developed in-house</td>
</tr>
<tr>
<td>2000</td>
<td>ELS spins off from</td>
</tr>
<tr>
<td>2000-01</td>
<td>Some new monitors sold with fixed software, others sold without fix.</td>
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<tr>
<td>May, 2002</td>
<td>Contract to supply 11 monitors to (Hospital)</td>
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<tr>
<td>Oct. 8, 2002</td>
<td>Japanese incident (burned, melted catheter)</td>
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<tr>
<td>Nov. 15, 2002</td>
<td>Supplies monitor used on Mr.</td>
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<tr>
<td>April, 2003</td>
<td>Corrective action plan re: software hazard</td>
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<tr>
<td>2003-04</td>
<td>3 of 11 monitors fixed</td>
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<tr>
<td>Oct. 11, 2004</td>
<td>Mr. ‘s heart is burned</td>
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<tr>
<td>Jan., 2005</td>
<td>Launched in U.S.</td>
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Contributing Factors to Incident

- Decision to wait for monitors to come in for servicing to replace software was flawed as there was no scheduled maintenance requirement for monitors.
- There was no requirement to replace cable after certain number of uses.
- Claimed hospital was negligent in not discovering recessed pins.
Research Results

- Because ELS failed to report Japanese incident, it took a lawsuit for the information to become discoverable.
- MAUDE Search revealed only the subject incident, aside from other non-related incidents.
- June 21, 2006 Recall of Vigilance I monitors.
Research Results, cont.

- Meier & Zieler, 1954
- Haller et al., 1995
- Mathews & Singh, 2006
- Paunovic & Sharma, 2007
- Chang & Nguyen, 2004
- Matthews, 2007
- Paunovic et al., 2006
- Zoremba et al., 2007
- Hadian & Pinsky, 2006
- Jansen, 1995
Findings

- **Layout 6** was probable root cause of subject incident
- FDA should have been notified of Japanese incident in 2002
- **ELS** failed to promptly fix or remove problematic software code
- Health care industry should have been notified of catheter-overheating potential and ways to avoid patient risk
- **ELS** could have provided cable continuity checker to assess possible recessed pins
In the News

- **Edwards LifeSciences** recalled all **Vigilance monitors** on June 21, 2006.

- **Jury awarded** $40.1 million to plaintiff and $310,000 to hospital.

- **Insurance company for Edwards LifeSciences** is **AIG**, which was just bailed out by the U.S. government.
Dialysis Water Treatment System

- Injuries and death caused by contaminated water
Dialysis Water Treatment System

- Incident involves a hemodialysis center located in Ohio
- Improperly maintained water treatment system led to contamination of dialysis center’s water supply
- Resulted in deaths of two people and hospitalization of 18 others
Samples from water treatment system showed high bacteria and endotoxin counts from 10,000 to 107,000 CFU/mL (Standard 200 CFU/mL)

8 of 12 samples from reverse osmosis had sulfur compounds
Documents Reviewed

- Deposition transcripts
- AFIP Investigation Report
- Medical Records
- Dialysis Center’s Service Records
- Policies & Procedures Manual
- Operations Manuals
Research Results

- Pontoriero et al, 2003
- Roth and Jarvis, 2000
- Bolan et al., 1985
- Arnow et al., 1994
- AAMI Standards and Recommended Practices, Volume 3: Dialysis, 1993
FDA MAUDE Reports

- 1423500-2004-00388
- 1423500-2003-00082
- 1423500-2002-01048
Sulfur smell coming from drain was routinely ignored
System Diagram - Normal Operation

Temperature Blending Valve: Mixes incoming hot and cold water.

Duplex Booster Pumps: Regulates incoming city water pressure to ensure adequate pressure to the system.

Water Softeners: Reduces concentration of calcium and magnesium.

Carbon Exchange Vessels: Absorb low molecular weight particles. Mainly used to remove chlorine and chloramines.

5 Micron RO Prefilters: Catch larger carbon fines prior to entering the RO unit.

Reverse Osmosis: Removes between 90 and 99 percent of bacteria, endotoxins, viruses, salts, and dissolved organics.

Citric Acid Feed: Lowers pH of incoming water.

Distribution Loop Feed

Mixed Bed Deionization Tanks: Removes ions and cations.

Storage Tank

0.2 Micron Post Filters

Figure 2: Normal Operation
System Diagram - Bypass

Temperature Blending Valve: Mixes incoming hot and cold water.

Duplex Booster Pumps: Regulates incoming city water pressure to ensure adequate pressure to the system.

Water Softeners: Reduces concentration of calcium and magnesium.

Citric Acid Feed: Lowers pH of incoming water.

Mixed Bed Deionization Tanks: Removes ions and cations.

0.2 Micron Prefilters

5 Micron RO Prefilters: Catches carbon fines prior to entering the RO unit.

Carbon Exchange Vessels: Adsorbs low molecular weight particles. Mainly used to remove chlorine and chloramines.

Reverse Osmosis: Removes between 90 and 99 percent of bacteria, endosporas, viruses, salts, and dissolved organics.

Distribution Loop Feed

Refrigeration System

Figure 3: Bypass Operation
Findings

- Staff frequently silenced controller/monitor alarms at central station without taking further action to determine cause.

- Staff members noted sulfur smell coming from water treatment system a month or more prior to incident; no action taken to understand origin of smell or to correct.

- Medical director said internal fluid pathways should be disinfected weekly and reverse osmosis unit monthly. This procedure was not followed.
Findings, cont.

- Water treatment system frequently put in bypass mode for extended periods
- Staff unaware of proper flush procedure for reverse osmosis system when turned off
- Reverse osmosis system not flushed during periods it was on bypass prior to incident
- Filters only changed every 6 months when they should have been changed every 3 months
News Related

- Bacteria found in Youngstown dialysis center
- National News - One dies 18 become ill
- Ohio Dialysis Accident Leaves 16 hospitalized 1 Dead
- Second patient dies after treatment at center
Conclusions

- If not already doing so, consider offering assistance to risk management
- Consider utilizing medical librarians and/or their databases
- If necessary, request outside assistance on matters
Always Remember *Murphy’s Law*

--Anything that Can Go Wrong Will

Then Add *Barkalow’s Motto*

for good measure

--Trust But Verify