Guidance Article

Investigating Device-Related “Burns”

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Current and previous issues are online at www.ecri.org (member access only).
Executive Summary

Featured in This Issue

Investigating Burns and Other Skin Injuries
Skin injuries sustained—or suspected of having been sustained—by patients in the operating room or special care areas of the hospital are often initially mistaken for thermal or electrical burns, with medical devices immediately blamed as the cause. However, such a hasty conclusion can overlook the actual cause of the injury and delay the implementation of measures to prevent future occurrences. In this month’s feature article (page 393), we describe a thorough investigation process to help healthcare facilities uncover the real cause of an accidental skin injury.

Identifying the Cause
Although certain medical procedures, such as electrosurgery, are known to present the risk of burns, it is important that staff not rush to judgment about the nature or cause of any injuries that do occur. Skin injuries are not always what they seem: What appears to be a device burn may instead be an abnormal or idiosyncratic physiologic response to otherwise normal conditions of device use and performance, or it may be due to pressure necrosis, an adverse drug reaction, or a disease process that happens to develop in the area where a device was applied.

Thus, when an accidental skin injury is suspected, healthcare facilities should initiate an investigation to determine both the nature and the cause of the injury. The following steps, as detailed in our Guidance Article, will facilitate the investigation process if an injury occurs:

- Always perform a preprocedure skin check, noting the general condition of the patient’s skin and any unusual conditions, and a postoperative check, noting any changes or abnormalities.
- If a device-related injury is suspected, preserve and document the evidence, especially all disposables and packaging.
- Ensure that relevant staff complete an incident report. The report should include only facts (e.g., “postoperative skin check revealed lesions on the patient’s heel”) and not speculation or supposition (e.g., “patient received electrosurgical burns on heel”).
- Discuss the issue honestly, but cautiously, with the patient and family. Again, stick to the facts as they are known at that time, and avoid speculation.

The article also offers specific guidance on how to conduct an investigation, including how to assess an injury to determine its cause and what device-specific factors most commonly contribute to such injuries.

ECRI’s Investigation Questionnaire
The questionnaire on pages 404 through 411 can be used by investigators to collect information during staff interviews and to summarize the baseline patient and equipment data that will be needed for the investigation.

Electrosurgical Safety Audit
This month, we follow up our August 2005 articles on electrosurgical safety with guidance on conducting a safety audit. The article identifies 10 key questions to ask of your facility as part of a safety audit. It also provides a starter list that facilities can employ to create a customized checklist for clinicians to use each time they perform electrosurgery. The article begins on page 414.

Also in This Issue

Evaluation Update: Baxter Colleague infusion pumps.
ECRI evaluated the Baxter Colleague CX and 3CX general-purpose infusion pumps in October 2002 and found the models to be Acceptable. Since that time, however, ECRI’s criteria have evolved to reflect the increasingly sophisticated capabilities of dose error reduction systems now on the market, and the two Baxter pumps have not kept up with advances in the technology. As a result, ECRI now rates these pumps Not Recommended for new purchases. See page 421 for details.

Thank you. In our annual Note of Thanks (page 422), we acknowledge some of the individuals outside ECRI who help us do what we do.

Problem reports. Fires that result during the use of external defibrillators in oxygen-enriched environments continue to occur, despite warnings from ECRI and other organizations. The Hazard Report on page 423 describes the problem and how hospitals should address it. Also this month, we describe how maneuvering Medcare Model 400001 and 400003 lifts in certain ways can damage the devices over time—a consequence that is not mentioned in the original training manual (see page 426 for details).
Investigating Device-Related “Burns”

Summary. Skin injuries sustained—or suspected of having been sustained—by patients in the operating room or special care areas of the hospital have many potential causes. Such injuries are often initially mistaken for thermal or electrical burns, with medical devices immediately blamed as the cause. However, such a hasty conclusion can overlook the actual cause of the injury and delay the implementation of measures to prevent future occurrences.

In this article, we describe a thorough investigation process to help healthcare facilities uncover the real cause of an accidental skin injury. Included is a detailed questionnaire to facilitate the investigation. We also present a list of potential causes of accidental skin injuries; these causes must be considered in a thorough investigation.
Identifying the Cause of an Accidental Skin Injury

Despite a great deal of care and concern by medical, nursing, surgical, and engineering personnel, patients do occasionally suffer inadvertent burns and other skin injuries in operating rooms (ORs) and in special care areas of the hospital—including recovery rooms, intensive care units (ICUs), and cardiac care units (CCUs). Such injuries can prolong morbidity and extend hospitalization, appreciably increasing medical costs to the patient and hospital; also, the hospital and surgical team may face liability costs if the injured patient brings suit.

Although certain medical procedures (e.g., electrosurgical procedures) are known to present the risk of causing device-related burns or other accidental skin injuries, it is important that staff not rush to judgment about the nature or cause of any such injuries that do occur. In its 35 years of investigating patient injuries and deaths from errors and accidents involving healthcare technology, instruments, devices, and systems, ECRI has observed that skin injuries are not always what they seem. The guidelines presented in this article will help healthcare personnel organize and conduct a thorough skin-injury investigation to identify the cause of an accidental skin injury. The questionnaire that accompanies this article facilitates the investigation process (see page 404).

Separating Fact from Fiction

When an accidental skin injury is suspected, healthcare facilities should initiate an investigation to determine both the nature of the injury and the cause. While these may appear obvious in particular cases, the seemingly obvious explanation for a skin injury is not always the correct one.

Medical devices are frequently blamed for accidental skin injuries, particularly for those that have the appearance of a full- or partial-thickness burn. However, thermal or electrical sources are not always involved. In many cases, the injury may be an abnormal or idiosyncratic physiologic response to otherwise normal conditions of device use and performance. Alternatively, the injury may be due to pressure necrosis, an adverse drug reaction, or a disease process that happens to develop in the area where a device was applied. (See “Etiologies of Accidental Skin Injuries,” on page 399.) It is therefore misleading—and in many cases inaccurate—to refer to such an injury as a “burn.” For these injuries, “lesion” is a more appropriate term because it allows the consideration of other causes.

When approaching the problem of skin injury, the following questions need to be addressed:

- What are the various kinds of skin injury, and where in the hospital do they occur?
- What procedures should be followed immediately after discovery of an injury?
- Who should be involved in an investigation?
- What information should be gathered?
- What measures should be implemented to prevent future occurrences?
- How and when should the hospital communicate with the manufacturer of implicated devices?

An understanding of the possible causes and effects of skin injury, combined with an effective investigation procedure, enables investigators to identify the actual cause of a particular injury and recommend precautions, thereby helping to minimize future risks to patients and to the hospital.

Building Blocks for a Thorough Investigation

FOR ALL SURGICAL PROCEDURES . . .

Be prepared. As described in the inset on page 395, steps taken before a surgical procedure can greatly facilitate the investigation of any skin injury that develops afterward. For example, information obtained during a preprocedure skin check—in which staff thoroughly examine the patient’s skin and note any unusual conditions—will allow staff to identify changes that might have occurred during or after the procedure.

Perform a postoperative skin check. As soon as possible following a surgical procedure, personnel should examine the patient’s skin and record any observed changes or abnormalities. In some cases, the patient’s physical condition may not permit an immediate and thorough postoperative skin check, but accessible areas (e.g., buttocks, heels, thighs, elbows, head, electrode sites) should be checked. The nursing staff should check other areas as soon as possible.
IF AN INJURY IS DISCOVERED . . .

Preserve and document the evidence. When a suspected device-related lesion is discovered, personnel should preserve and thoroughly document the evidence, especially all disposables and packaging. Contaminated disposables or other instruments should be stored in appropriate biohazard containers. When practicable, color photos of the skin injury should be taken immediately after discovery and 24 and 48 hours afterward (permission from the patient or family may be necessary). Photographs should provide some indication of the scale of the lesion (e.g., using a coin or ruler).

If possible, surgical and medical personnel should not move or disconnect the equipment, except as necessary to care for the patient or to prevent further injury or equipment damage. When it is not possible to preserve the physical setup of the involved equipment and devices, personnel should record the scene with photographs or sketches. Color photographs should be taken before inspection of devices that may be damaged when examined, such as a disposable dispersive electrode for use with an electrosurgical unit (ESU).

Ensure that no involved materials or devices are released to the manufacturer until completion of the internal incident investigation or until approval has been given by risk management or administration. Note, however, that facilities in the United States may be required to submit a timely report to the manufacturer in compliance with U.S. Food and Drug Administration (FDA) regulations.

Complete an incident report. The head nurse of the department in which the injury occurred should fill out an incident report and record the immediate observations of all involved personnel. To avoid premature or inaccurate conclusions, the incident report should include only facts, not speculation or supposition. For example:

- **Incorrect:** “Patient received electrosurgical burns on right buttock and heel.”
- **Correct:** “Postoperative skin check revealed lesions on the patient’s right buttock and heel.”

The head nurse should make sure that all personnel involved in the incident complete incident reports as well.

Discuss the injury honestly, but cautiously, with the patient and family. Discussion with the patient and family about the injury should be honest and cautiously diplomatic. The actual cause of the injury probably will not be known before the incident is discussed with the patient. As such, offering specific theories can be misleading and provoke litigation.

For example, if a patient develops a palm-sized lesion over the sacrum on the day following a lengthy cardiovascular surgical procedure, pressure necrosis is the probable cause. But we know of many cases like this in which the nursing, medical, or surgical staff told the patient, “The electrosurgical machine accidentally burned you during the surgery.” Such statements frequently lead the patient to seek legal counsel, sometimes even before leaving the hospital. A more productive and factual approach is to tell the patient that there is “an injury” or “an area of skin breakdown” and that it will be treated. In some cases, it may be suitable to mention that the cause is being investigated.

The Investigation Process

An investigation need not be a threatening experience for anyone. The goal of the investigation is to determine what happened and recommend appropriate preventive measures—not to assign blame. This should be explained to all personnel involved in the incident.
ASSEMBLING THE INVESTIGATION TEAM
The investigation team should include staff members who are familiar with the equipment used and the environment in which the incident occurred. The team might include a clinical engineer, an OR or critical care nurse (frequently the supervisor for one of these departments), a physician, an equipment technician, and the risk manager. The risk manager will help ensure that proper steps are taken to preserve confidentiality and maintain legal compliance.

The chosen coordinator should understand the various mechanisms of skin injury and the investigative process. To ensure objectivity, no one who had primary responsibility for the patient before or after the injury should be included on the team. Also, the team must be careful to fairly represent different interpretations of the incident: what one person calls operator error may be interpreted by someone else as inadequate equipment design or a device failure.

It may be beneficial to deploy qualified, independent external investigators in some cases. For example, the hospital may lack the in-house expertise to investigate the incident; also, the potential for bias or concealment exists in any in-house investigation. External investigators can be helpful in exploring both technical and legal issues, especially when litigation is likely. Because they have no preconceived notions, external investigators are usually objective and cooperative, rather than defensive or adversarial. With in-house investigators, there may be the risk of damaging long-term working relationships.

IDENTIFYING THE CAUSE
When trying to ascertain the cause of an accident, ECRI has historically considered the five broad categories listed below. Within each of these categories, we have listed the relevant subcategories that should be considered when investigating suspected device-related burns. To ensure thoroughness and accuracy, each of these must be considered in any investigation.

1. Device Factors
   — Device failure
   — Device interaction
   — Design/labeling error
   — Failure of an accessory
   — Improper maintenance, testing, or repair
   — Manufacturing error

2. User or Use Error
   — Abuse of the device
   — Accidental misconnections
   — Improper (“bad”) connection
   — Device misassembly
   — Failure to monitor
   — Failure to heed labeling
   — Inappropriate reliance on an automated feature
   — Incorrect clinical use
   — Incorrect control settings
   — Maintenance or incoming inspection error
   — Failure to perform pre-use inspection

3. Facilities Factors
   — Water supply (especially temperature)

4. Tampering/Sabotage
   — Device user (clinician)
   — Device user (patient)
   — Family member or enemy
   — Random act

5. Support System Failure
   — Poor prepurchase evaluation
   — Poor incident/recall reporting systems
   — Failure to impound incident-related devices
   — Lack of competent accident investigation
   — Failure to train and credential
   — Use of inappropriate devices
   — Lack of incoming inspections
   — Improper cleaning, sterilization, or storage

In addition, it must be remembered that a patient may have specific physiologic sensitivities, abnormalities, or diseases. As such, a patient’s suspected “burn” injury may ultimately be determined to be an abnormal or idiosyncratic physiologic response to otherwise normal conditions of use and performance for that device. It may also be determined that a technology was not involved at all.

ACTING QUICKLY
Time is a significant factor in starting and completing an investigation. The longer it takes to mount and complete an investigation, the greater the probability that the cause will grow elusive as evidence is lost, memories dim, defensive rationalizations crystallize, and speculation clouds the process. In addition, if there is a reason to suspect medical-device-related injuries, there is a limited timetable for submission of a report to the manufacturer (e.g., to meet FDA regulations) or to appropriate regulatory bodies.
The Investigation Format

A thorough investigation of accidental skin injury should include the following:

- Consideration of the incident report and collected evidence, such as photographs
- Collection of baseline patient and equipment information
- Documentation and assessment of the lesion’s appearance and progression
- Inspection and testing of equipment used
- Interviews with involved personnel

Before performing equipment inspections and interviews, the investigation team should review and be familiar with the clinical and surgical procedures and conditions surrounding the incident, as well as understand the lesion’s clinical appearance and collect the baseline information.

BASELINE INFORMATION

Baseline information on both the patient and the equipment is required for the investigation. Much of the patient baseline information will come from the patient’s chart. Before any interviews are conducted, the patient’s chart should be thoroughly reviewed because it will indicate the hospital personnel most appropriate to be interviewed.

The investigation team should make sure that equipment information is recorded for all devices involved in the incident, including disposables. For devices that are routinely inspected, the date of the “last” inspection and the “due” date must be recorded. If available, the equipment performance history should also be reviewed.

LESION ASSESSMENT

Details about a lesion’s clinical appearance and progression are important to determining its cause. A guide for collecting critical information about the lesion can be remembered by using the mnemonic OPALSS—Onset, Progression, Appearance, Location, Shape, and Size. These six descriptive criteria are central to assessing the cause of a lesion and the potential involvement of a medical device. For example, pressure necrosis injuries (decubitus ulcers) from intraoperative pressure may show up several days after the insulting event, whereas electrosurgical burns are visible immediately at the end of surgery and do not suddenly appear days later.

The following list illustrates how the OPALSS criteria can be applied to obtain needed details about a lesion. The list is not intended to be all-inclusive, but rather to stimulate thinking during the investigation.

- **Onset**
  - When was the lesion discovered? Get the precise time and date.
  - When did surgery occur?
  - How long was the patient immobile in the recovery room or ICU after surgery?
  - At what time was the last heat-therapy device or heated product used on the patient, and how long was it applied?
  - Where was discovery made and by whom?

- **Progression**
  - After discovery, did the lesion get larger, deeper?
  - Did blisters form? When?
  - Did an eschar form?

- **Appearance**
  - What did the lesion look like upon discovery?
  - Note the color and texture of both the central area and the surrounding areas.

- **Location**
  - Where on the body was the lesion?
  - Record its location in relation to electrodes, high-pressure areas of contact, and positioning devices.
  - Is there a clearly definable electrical current path through the area of injury? Specify the validity of the alleged current path in collaboration with engineering staff.

- **Shape**
  - Note the geometry of the lesion.
  - Are there patterns of devices or electrodes within the lesion?
  - Does the shape correspond to heat-therapy devices or electrodes?

- **Size**
  - Measure the injury dimensions.
  - What is the area of the injury, including all affected tissue area (e.g., perimeter halos)?
  - If there are multiple lesions, what is the combined area?

Changes in the lesion should be noted as the injury progresses or heals. Color photographs are the best way to document changes in the condition of the injury. The time,
date, and scale should be recorded for each photograph. The same lighting conditions should be maintained when taking photographs.

**EQUIPMENT INSPECTION**

After discovery of a suspected device-related skin injury, all equipment that may be involved, including disposables, should be sequestered until it has been inspected. Most equipment can be immediately returned to service because it will be obvious that it played no role in the injury. However, no suspect device should be returned to service until it has been eliminated as a possible cause of the injury.

The manufacturer should not be permitted to remove equipment or disposables from the hospital because the hospital then loses all access to them. The hospital should not send such devices to their suppliers without approval from risk management or administration, nor should suppliers be permitted unwitnessed access to the devices for inspection or repair. In many cases, evidence that might protect the hospital could be lost or compromised.

Depending on the nature and location of the injury, the equipment, devices, and solutions that may have to be inspected might include the following:

- ESUs and accessories, such as active electrodes, dispersive electrodes, cables, and electrode gels
- Hypo/hyperthermia units, with associated blankets and patient temperature probes
- Blanket and solution warming cabinets
- Heat lamps and heating pads
- Lasers and laser fibers
- Diathermy units
- Endoscopes, with their light sources
- Transilluminators
- Pulse oximeters and pulse oximeter probes
- Nerve stimulators and stimulator electrodes
- Intra-aortic balloon pumps
- Tourniquets
- Monitors such as ECG, EEG, and temperature, with associated cables, electrodes, and probes
- Cardiopulmonary bypass equipment
- Beds
- OR tables
- Anesthesia masks and tubing
- Prepping and degreasing agents
- Ointments
- Linens

Personnel who are normally responsible for maintaining and inspecting the incident equipment should not inspect it following an incident, as such individuals may not recognize past errors or may even try to conceal them. If alternate technical personnel are not available, an outside, independent examination of equipment may be most effective. The manufacturer may want to witness equipment inspections, and it is usually in everyone’s best interest that this be permitted. Inspections are best undertaken by the hospital’s risk manager and clinical engineer, an outside investigator, and the manufacturer simultaneously.

**INTERVIEWS AND DATA COLLECTION: USING ECRI’S QUESTIONNAIRE**

The questionnaire on pages 404 through 411 is a guide for collecting information during interviews, as well as for summarizing baseline patient data and recording necessary details about each device involved in the investigation. One copy should be completed for each person involved in the incident. Relevant questions should be directed to all appropriate people because multiple responses will help corroborate data on the time and sequence of events. Although it is unlikely that any one person will be able to answer all the questions, everyone can provide useful information based on his or her general observations and discussions with other personnel involved in the incident.

**In Summary . . .**

A thorough investigation of a skin injury includes consideration of all possible device and/or solution interactions. It must also consider the possibility that the injury was an allergic reaction, a disease, or an idiosyncratic response. While it is easy to assume that a certain device or solution caused the injury simply because it was used, such assumptions are often incorrect and may preclude considerations of other possibilities. Hasty conclusions that a device or an operator was at fault may bias the investigation, mislead the patient into bringing suit, and unjustly impugn personnel, equipment, service organizations, or manufacturers.

The investigation team must make sure that all possibilities are explored and that everyone involved in the incident is questioned. Only then will it be possible to develop effective preventive measures.
# Etiologies of Accidental Skin Injuries

## Electrical
- Radio frequency (RF)—electrosurgery, magnetic resonance imaging (MRI) RF coils
- DC—batteries, circuit continuity monitors, pacemakers, nerve and muscle stimulators
- AC—60 Hz line voltage

## Thermal
- Direct contact—heating pads, electrocautery, diathermy, heated irrigation solution bag, excessively heated cotton blanket, unlubricated surgical drill shank, flash-sterilized surgical instruments, heated probes
- Irradiant—radiant warmers, exam and operating lights, fiberoptic light cables, lasers
- Exothermic chemical reaction—Merthiolate on aluminum electrode

## Chemical
- Povidone-iodine prep solutions—problems with lot-specific formulation, solution pooled under a patient that reacts with other solutions or with residual laundry chemicals in linens, mixing with alcohol or hydrogen peroxide
- Ethylene oxide (EtO)—improper aeration of EtO-sterilized devices
- Improper electrode plating components reacting with conductive paste

## Mechanical
- Constant high pressure in excess of two to three hours (e.g., caused by positioning contours, supports, straps, pinching); time required may be shorter with very high pressure
- Pneumatic tourniquets
- Tenacious electrode adhesive

## Radiation
- Diagnostic imaging
- Therapeutic treatment

## Pharmacologic
- Warfarin therapy (e.g., Coumadin)
- Intra-arterial injection of Bicillin (penicillin G)
- Drug infiltration at a catheterization site
- High-dose injected barbiturates injection in subcutaneous or fat layer

## Physiologic/Medical
- Allergic reaction (e.g., to adhesives, electrode gel, ointment, or skin prep solution)
- Aplasia cutis (neonates)
- Chronic chilblain (pernio)
- Ecthyma gangrenosum
- DIC (disseminated intravascular coagulopathy)
- Lesions secondary to lupus erythematosus or Hodgkin’s disease
- Lichen sclerosus et atrophicus
- Livedo reticularis (including idiopathica)
- Purpura fulminans
- Necrotizing fasciitis (“flesh-eating bacteria”)
- Ischemic lesions resulting from:
  - Peripheral vascular disease
  - Venous stasis
  - Diabetes mellitus
  - Cryoglobulinemia
  - Arterial emboli of atherosclerotic plaque (blue toe syndrome)—iatrogenic, intraoperative, or otherwise
  - Anterior compartment syndrome
Investigation Questionnaire
Accidental Skin Injuries

ECRI developed the questionnaire presented on pages 404 through 411 to help investigators gather information about accidental skin injuries. The form serves as a guide for collecting information during interviews, as well as for summarizing baseline patient data and recording necessary details about each device involved in the investigation. Although the questionnaire is designed for skin injuries that occur in the OR, it may also be used to investigate skin injuries that occur in the recovery room and special care areas or skin injuries noticed on any patient exposed to heating and illumination devices, tenacious tape or electrode adhesives, or prepping and degreasing agents.

The questionnaire is divided into five main sections:

A. Baseline Patient Information
B. Baseline Equipment Information
C. The Surgical Procedure
D. The Injury
E. The Equipment

These sections are discussed below. Additional sections for the interviewer’s and the interviewee’s summary comments are also provided.

Instructions
- Record the baseline patient and equipment information (Sections A and B).
- Make a separate copy of the partially completed questionnaire for each person who is to be interviewed. Relevant questions should be directed to all appropriate people because multiple responses will help corroborate data on the time and sequence of events. Although it is unlikely that any one person will be able to answer all the questions, everyone can provide useful information based on his or her general observations and discussions with other personnel involved in the incident.
- Record the interviewee’s answers to all relevant questions in Sections C through E.
- Note: Most information can be recorded directly on the questionnaire form. If needed, lengthy answers to questions or device identification details can be recorded on a separate sheet of paper with the numbers corresponding to the questions. Be sure to record the interviewee’s name and your name on all attached sheets.
- File the completed questionnaires with the incident report. The questionnaires should not be filed with the patient’s record.

Collecting and Analyzing the Data

A. BASELINE PATIENT INFORMATION
The need for baseline patient information is self-evident.

B. BASELINE EQUIPMENT INFORMATION
Information about each involved device, including disposables, will also be needed for a thorough investigation to be conducted.

C. THE SURGICAL PROCEDURE
Patient surgical and medical records typically provide information that is only marginally useful in determining the cause of a suspected device-related injury. The investigation team must interview all surgical, medical, and nursing staff involved in the procedure and in the postoperative care of the patient. It may also be necessary to question technicians and other personnel responsible for cleaning, sterilizing, inspecting, or maintaining the equipment and supplies used for the injured patient.

Investigators should pay special attention to information concerning any unusual occurrences during the procedure. For example, they should ask about occurrences such as the following:
- Changes in device performance
- Unattended devices
- Peculiar sounds, monitor displays, smells, or alarms
- Sudden changes in the patient’s condition or physical position

Investigators must also determine how solutions, degreasers, and prepping agents were applied during the procedure. During routine surgery, there is usually enough time to apply these substances carefully. During emergency
surgery, however, sometimes not enough care is taken, and too much prepping agent is applied. This can result in pooling beneath the patient. After exposure for several hours to these substances, a sensitive patient may develop lesions. A patient may be sensitive to the prepping agent itself, and the application of heat from a hyperthermia blanket, for instance, may increase that sensitivity. Even the wetness alone can compromise skin tone and make it more susceptible to developing pressure necrosis.

D. THE INJURY

The anatomical drawing on the questionnaire enables investigators to locate lesions in relation to the incision site, dispersive electrodes, stimulation electrodes, ECG electrodes, and all associated cables. Any contact between the patient and metal (e.g., drape supports on the side of the operating table, mechanical supporting instruments such as retractors) or conductive tubing and masks should also be recorded.

Lesion patterns can help identify the causes. When an ESU is used, incomplete contact of an electrosurgical dispersive electrode with the patient may produce a lesion identical to a section of the electrode’s perimeter. Or when a hypo/hyperthermia blanket is used, lesions that conform to the blanket’s ridges may appear on the sacral areas, while no other area of the skin that was touching the blanket shows any injury. In this case, the blanket was probably not hot enough to cause thermal injury from simple contact; possible causes are pressure necrosis (perhaps in combination with mild heat) and ethylene oxide (EtO) residue (in a reusable hyperthermia blanket).

The investigation team should pay attention to when the injury was discovered and to any subsequent changes. While a lesion on the patient’s back or sacral area may have been discovered several hours postoperatively in the recovery room or intensive care area, it may have actually occurred in the OR, but was aggravated by the patient’s position during postoperative care. The patient’s treatment and medication and other comments regarding the progression and prognosis of the lesion should also be recorded.

Determining the etiology of an injury may be aided by histological examination of skin or tissue pathology specimens. Such specimens may have been taken during debridement. Pathology findings may be able to reveal whether the injury was caused by a disease, by electrosurgical current, or by thermal injury.

E. THE EQUIPMENT

Electrodes. Care should be taken when handling electrodes (e.g., electrosurgical, nerve stimulation, and EEG electrodes) used during a procedure in which an injury may have been sustained. For example, suspect electrodes with adhesive borders or conductive adhesive should not be folded over on themselves. Rather, they should be applied to a nonstick material, such as the backing material with which the electrode was packaged. If necessary, a new electrode can be opened and its nonstick backing can be applied to the suspect electrode. Doing so will help prevent the electrode from drying out and makes subsequent testing easier and more likely to produce useful results.

ESUs and accessories. Information obtained from interviews about the performance and control settings of the ESU should be compared with the results from equipment inspections. If the unit meets proper performance specifications (e.g., the manufacturer’s specifications), it can be returned to service.

In most cases of skin injury involving ESUs, the cause of the injury is related to the electrodes, cables, or other accessories, rather than improper functioning of the unit itself. For example:

- Insufficient contact, improper electrode placement or size, an inadequate amount of gel, pressure on the pad, or a defective electrode can contribute to lesions beneath the dispersive electrode.

- Defective cables and connectors may cause electrosurgical currents to seek alternate return pathways through the patient, resulting in injuries at locations other than the incision or return electrode sites.

Poor electrical continuity in either the return electrode or the cables can lead to difficulty achieving the desired surgical effect, which in turn can lead the surgeon to request more power. However, increasing the power setting under conditions of poor continuity usually does not result in the expected increase in ESU performance, and the surgeon may again request more power if poor continuity is not recognized as the cause of the problem. Continued use of the ESU in this manner increases the likelihood of a burn either at the site of the return electrode or at an alternate site. Staff education that emphasizes intraoperative checking of ESU electrodes and cables if a problem is suspected and the use of a return-electrode contact-quality monitor (RECQM) can minimize the risk of injury from a partially or fully detached return electrode or a damaged cable.

If a lesion is found beneath the electrosurgical dispersive electrode (also called the ground plate or patient
plate), surgical personnel should inspect the electrode immediately for discoloration, obvious damage, wetness of the gel, evidence of contact with fluids, and those other characteristics listed in the questionnaire. Comparison with a new electrode is helpful in determining subtle differences with the suspect electrode. The investigator should also observe whether the entire conductive or capacitively coupled surface had been in contact with the patient’s skin. It should also be noted whether straps were placed over the electrode or whether a member of the surgical team leaned on it or stepped on its cable and caused partial dislodgment. Pressure on a disposable return electrode or partial dislodgment may cause localized high current densities, which can cause burns. Later inspections should be performed to determine whether there are any discontinuities or separations of the connector and/or of the conductive substrate (usually made of foil) or whether a part of the electrode is missing.

The type of ESU can be a factor in the cause of alternate-site burns. Typically, ground-referenced ESUs will more likely be associated with an alternate-site burn than isolated-output units. However, the investigator should be aware that isolation can fail and that, under certain operating conditions (e.g., open-circuit activation), a properly operating isolated-output unit could cause an alternate-site burn from current originating at the return electrode.

Hand-switched active electrodes, both disposable and reusable, must also be inspected. A defective switching mechanism of a hand-switched active electrode can cause inadvertent activation of the ESU and result in burns. Insulation failure can also cause a burn where the section of the electrode with missing or poor insulation contacted the patient. Determine where the active electrode was placed between uses. Injury from inadvertent activation would be more likely if the electrode was not placed in a well-insulated safety holster.

➤ For more information about managing burn risks during electrosurgical procedures, especially those involving high-current electrosurgery, refer to the collection of articles on electrosurgical safety in the August 2005 Health Devices. Also refer to the discussion of electrosurgical safety audits on page 414 of the current issue.

Hypo/hyperthermia units and radiant warmers. In most cases of intraoperative skin injury attributed to hypo/hyperthermia blankets, the unit proves to be operating properly; other causative mechanisms (e.g., pressure necrosis) must then be considered. Lesions resulting from exposure to radiant warmers are commonly caused by operator error, device malfunction, or poor device design. With both blankets and warmers, it is important to inspect the units in all possible operating modes, both with and without the actual temperature probe used on the patient plugged into the machine. Primary and redundant thermostat failure, misadjustment, or faulty calibration may not be discovered except under very specific, abnormal operating conditions.

In addition to general information on the use of the equipment, the team should review cleaning and sterilization procedures for the hypo/hyperthermia blanket. It should also review the placement of the temperature probe on the patient. A blanket that has been sterilized with EtO and not aerated adequately can cause a chemical lesion during prolonged contact.

Manipulation or repositioning of the patient after insertion or placement of the temperature probe (rectal, esophageal, or skin) can dislodge the probe. Depending on the operating mode, this may cause a hypo/hyperthermia unit to heat even though it was set to cool the patient. A dislodged probe on a radiant warmer can cause it to constantly heat, even if it was set to cycle on and off.

Blanket and solution warming cabinets. Warming cabinets are used to heat blankets and solutions (e.g., for surgical irrigation, for intravenous infusions) for patient comfort. Warmed blankets are often placed on patients to make them feel more comfortable in cool ambient temperatures or when sedation or anesthesia has disturbed the body’s thermal regulation. Warmed solutions are used to prevent hypothermia caused by infusion of lower-temperature liquids into a patient’s body. Most warming cabinets have separate compartments and temperature settings for blankets and solutions.

In response to customer demands, suppliers have designed some cabinets so that they can be set to a wide range of temperatures. Unfortunately, this allows the cabinets to heat blankets and solutions to temperatures that can cause contact burns to patients’ skin.

Patients have received burns during surgery because warmed blankets or solutions were too hot. Such thermal injuries typically occur with patients who are unconscious or who have been given regional (e.g., spinal) anesthesia and are therefore insensate to temperature. Many incidents have involved solution containers (e.g., IV bags) that have been heated to unsafe temperatures and then used as positioning aids during surgery or as “hot water bottles” to
provide local heat. In other incidents, overheated solutions have been used for surgical irrigation, causing severe internal injury. And blankets that have been excessively heated and placed on or under the patient have caused burns; in some cases, the blankets were folded in layers.

➤ For more information on preventing burns from overheated solutions and blankets, see the Hazard Report on page 168 of the May 2005 Health Devices.

Endoscopes and accessories. Endoscopes (e.g., laparoscopes) and their accessories, such as trocars and sleeves, are frequently used in combination with electrosurgery. The use of monopolar electrosurgery during minimally invasive procedures, such as laparoscopy, introduces risks that are not typically encountered during open procedures. For example:

- Current can become concentrated within narrow internal pathways, leading to excessive heating of internal structures.
- Contact between an activated electrode tip and other conductive instruments within the patient can cause those instruments to become energized, possibly leading to a burn.
- Stray electrosurgical energy (leakage current) from the shaft of the active electrode can pass through gaps in the insulating material or across the intact insulation by means of capacitance to other instruments or internal tissues.

Any of these events can create burns within the body, and some of these burns, such as those that lead to bowel perforations, can be fatal. Laparoscopic electrosurgical handpieces should be inspected for any damage or deterioration of the insulation from repeated sterilization or physical abuse.

➤ For more information about managing burn risks during laparoscopic electrosurgical procedures, see “Safety Technologies for Laparoscopic Monopolar Electrosurgery” in the August 2005 Health Devices.

Another issue to consider with endoscopes is the use of high-powered light sources, which generate a significant amount of heat and can lead to burn hazards such as the following:

- Burns from the light itself. For example, when the fiberoptic cable is disconnected from the light source, the beam of light freely streaming from the light source can generate enough heat to burn objects in close range, or even start a fire.
- Burns from heat conducted to metal connectors on the cable. This can happen if the size of the light cable is poorly matched with the instrument’s light post and/or the receptacle on the light source or if too many of the cable’s fibers are broken and thus won’t carry light. The generated heat has to go somewhere, and usually it is transferred to the metal connectors. While the resulting heat isn’t typically enough to start a fire, it can definitively cause serious burns to patients and operators.

The investigation team should determine whether the light cable was removed from the light source or whether the instrument (e.g., laparoscope) was removed from the light cable while the light source was still turned on. The team should further note the placement of the light source and light cable in relation to the patient. Light cables should be inspected to make sure that they are appropriately matched to the light source and that there is not an excessive number of broken fibers in the cable.

➤ For more information on preventing burns and fires caused by high-powered light sources, refer to the Hazard Report on page 325 of the September 2005 Health Devices.

Pulse oximeters. Burns and other skin injuries have been associated with the use of pulse oximeters. Pulse oximeters are used during most surgical procedures, including electrosurgery, and pulse oximeter probes have provided alternate pathways for electrosurgical currents. Also, skin injuries have occurred at pulse oximeter probe sites from pressure necrosis, and mismatching of pulse oximeter probes and monitors has resulted in excessive heating of the probe LEDs. Burns have also occurred during magnetic resonance imaging (MRI) procedures.

If pulse oximeter involvement is suspected, carefully inspect the probe and its cabling, note the location of the probe and how the cable was draped, and note whether the probe site was changed during the procedure. Because pulse oximeter and probe compatibility is a potential cause of injury, note whether the probe was used with the appropriate pulse oximeter monitor.
Accidental Skin Injury Investigation Questionnaire

Date of Interview: ________________________________________________________________

Interviewee:
Name ____________________________________________________________
Title/department ____________________________________________________________________
Job function during incident ________________________________________________________

Interviewer:
Name ____________________________________________________________
Department _______________________________________________________________________

A. Baseline Patient Information

1. Name ________________________________________________________________
2. Hospital ID No. _________________________________________________________
3. Sex ________________________________________________________________
4. Age _________________________________________________________________
5. Race _________________________________________________________________
6. Skin color and skin description (e.g., mottled)
   ________________________________________________________________
   ________________________________________________________________
   ________________________________________________________________
7. Weight _______________________________________________________________
8. Diagnosis ___________________________________________________________
   ________________________________________________________________
   ________________________________________________________________
9. Known allergies _______________________________________________________
   ________________________________________________________________
10. Known circulatory problems ____________________________________________

Instructions

Record the baseline patient information (Section A) and baseline equipment information (Section B). Note that Section B will need to be completed for each involved device, including disposables; thus, it may be necessary to make multiple copies of that page.

Make a separate copy of the partially completed questionnaire for each person who is to be interviewed.

Record the answers to all relevant questions in the remaining sections. Attach additional sheets, if needed; be sure to record the interviewee’s name and your name on all attached sheets.

File the completed questionnaires with the incident report. The questionnaires should not be filed with the patient’s record.

Source. This form was developed by ECRI. A detailed discussion of how to use this questionnaire is included in the December 2005 issue of ECRI’s monthly journal Health Devices.
### B. Baseline Equipment Information

Copy this page and record the following information for each involved device (including disposables). Attach all completed copies to the questionnaire.

<table>
<thead>
<tr>
<th>Device ____ of ____</th>
<th>Device ____ of ____</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Device type __________________________</td>
<td>1. Device type __________________________</td>
</tr>
<tr>
<td>2. Manufacturer _________________________</td>
<td>2. Manufacturer _________________________</td>
</tr>
<tr>
<td>4. Serial and/or Lot No._________________</td>
<td>4. Serial and/or Lot No._________________</td>
</tr>
<tr>
<td>5. Hospital Equipment Control No.__________</td>
<td>5. Hospital Equipment Control No.__________</td>
</tr>
<tr>
<td>6. Expiration date or “use before” date _______</td>
<td>6. Expiration date or “use before” date _______</td>
</tr>
<tr>
<td>7. “Last” and “due” inspection dates_________</td>
<td>7. “Last” and “due” inspection dates_________</td>
</tr>
<tr>
<td>8. Any outstanding recalls or Action Items regarding this device* __________________</td>
<td>8. Any outstanding recalls or Action Items regarding this device* __________________</td>
</tr>
<tr>
<td>9. If reusable, method of sterilization or cleaning _____________________________</td>
<td>9. If reusable, method of sterilization or cleaning _____________________________</td>
</tr>
<tr>
<td>10. For endoscopes and endoscopic instruments, also record the following:</td>
<td>10. For endoscopes and endoscopic instruments, also record the following:</td>
</tr>
<tr>
<td>a. Generic type (e.g., laparoscope or laparoscopic forceps, resectoscope, colonoscope) __________________</td>
<td>a. Generic type (e.g., laparoscope or laparoscopic forceps, resectoscope, colonoscope) __________________</td>
</tr>
<tr>
<td>b. Endoscope type</td>
<td></td>
</tr>
<tr>
<td>i. Operating or diagnostic (circle one)</td>
<td>i. Operating or diagnostic (circle one)</td>
</tr>
<tr>
<td>ii. Direct viewing or video (circle one or both)</td>
<td>ii. Direct viewing or video (circle one or both)</td>
</tr>
<tr>
<td>c. Trocar sleeve type—metal, plastic, other __________________________</td>
<td>c. Trocar sleeve type—metal, plastic, other __________________________</td>
</tr>
<tr>
<td>d. Light source and fiberoptic cable used __________________________</td>
<td>d. Light source and fiberoptic cable used __________________________</td>
</tr>
<tr>
<td>e. Special connectors or adapters __________________________</td>
<td>e. Special connectors or adapters __________________________</td>
</tr>
</tbody>
</table>

* Members can search ECRI’s Health Devices Alerts database for Action Items and other information about device hazards and recalls. To access this database, visit www.ecri.org, log in as a member, go to your membership home page, and select the Health Devices Alerts option.
C. The Surgical Procedure

1. Procedure ________________________________________________________________

2. Date performed and OR No. __________________________________________________

3. Time duration ____________________________________________________________

4. How many procedures of this type are performed per month? __________________

5. Was this an elective or emergency procedure? ________________________________

6. Who was present during the procedure? ______________________________________

7. Who performed the following tasks? When?
   a. Applied degreasing and prepping agents _________________________________
   b. Applied ESU dispersive electrode _______________________________________
   c. Applied surgical drapes _________________________________________________
   d. Inserted hypo/hyperthermia temperature probe ___________________________
   e. Set up ESU and connected cables _______________________________________
   f. Set up endoscope and accessories _______________________________________
   g. Applied any other electrodes, temperature probes, etc. ___________________

8. Was a skin check performed before the procedure? By whom? Results? __________

9. Was the patient wearing jewelry or any other items during the procedure? ______

10. What degreasers, prepping agents, and ointments were used? __________________

11. How were they applied to the patient? Were they poured onto the skin? ________

12. Was there pooling of fluids beneath the patient? ___________________________

13. Were prepping agents dry before draping? _________________________________

14. What was the patient’s initial position on the operating table? For how long? ______

15. In what position(s) was the patient placed for surgery? For recovery? ___________

16. Were any changes made in the patient’s position during surgery? Describe. _______
17. What types of restraint straps or positioning pads were used to position the patient? Describe their location.
________________________________________________________________________________________
________________________________________________________________________________________

18. What, if anything, occurred during the procedure that was out of the ordinary? Any alarms or unusual noises?
________________________________________________________________________________________
________________________________________________________________________________________

19. How well does the user understand the equipment controls, functions, and safety features?
________________________________________________________________________________________

D. The Injury

1. Mark on the anatomical drawing the position and shape of the following items:
   a. Skin injuries
   b. ESU dispersive electrode
   c. ECG electrodes and cables
   d. Extent of prepping
   e. Incision (or site of active electrode)
   f. Restraint straps
   g. Patient/metal contacts
   h. Conductive masks and tubing

2. When and where was the lesion noticed (e.g., during surgery, postop, or recovery; in the patient's room)?
   By whom? __________________________________________
   __________________________________________
   __________________________________________

3. Did the lesion correspond to the position of an electrode, a cable, or patient/metal contacts?
   __________________________________________

4. Does the patient have any metal implants (e.g., hip, knee)?
   __________________________________________

5. Sketch the shape of the lesion in the space provided.
Guidance Article

Investigation Questionnaire: Accidental Skin Injury

6. Give the dimensions. ________________________________________________________


8. Describe lesion tissue color, texture, size, and location when first noticed and as healing progressed. ____________________________________________________________

9. Were photographs taken? Record the dates and times, and note the scale. ______________________

10. Were skin or tissue specimens from the injury retained? Pathology findings? ________________________

11. Describe the treatment and medication applied to the injury. ______________________________________

12. Did infection of the lesion occur? How soon? ________________________________________________

13. Comments by patient regarding the level of pain at the injury site. ____________________

E. The Equipment

1. Sketch the positions of equipment, cables, and leads relative to the patient. Do this for operative, recovery room, and general care settings, as appropriate. Use separate sheets if needed, and attach them to the questionnaire. If known, indicate where equipment was plugged in and the relative distance from the patient and other equipment.

2. Describe the condition of all cables, leads, and connectors. ______________________________________

3. Document all switch, control, and indicator settings on all devices used. Were these settings typical for the procedure? ____________________________________________

4. If a device that was EtO sterilized was touching the lesion, how was the device aerated? _________________

5. Who had contact with the suspect equipment after the incident? ____________________________

6. Were any inspections or repairs performed? Results? ____________________________________________
7. Have there been any recent malfunctions of devices used in this procedure or similar procedures? Does the injury possibly relate to device malfunctions recently experienced? Were there any malfunctions during the procedure? (Review equipment service records for possible information.)

________________________________________________________________________
________________________________________________________________________
________________________________________________________________________

8. Was the packaging from suspect disposables saved? ____________________________________________

9. **Electrosurgery**
   a. Determine the following:
   i. What was the mode of operation (cut, coag, blend, bipolar)? ______________________________
   ii. What were the control settings for each mode? ____________________________________________
   iii. What electrode adapters were used? ____________________________________________________
   iv. Does the ESU have a ground-referenced or isolated output? ________________________________
   v. Does the ESU have a return-electrode contact-quality monitor (e.g., return electrode monitor)? If so, was it used? ____________________________________________

   b. Was the condition of the ESU cables and connectors checked before surgery? ______________

   c. Was electrosurgery effective at normal settings? ___________________________________________


   e. Describe the condition of dispersive and active ESU electrodes after the procedure.
      Discolored? Charred? Evidence of fluid contact? _____________________________________________

10. **ESU Dispersive Electrode**
   a. Describe the gel condition before and after use. Dry to touch? Viscous or runny? Color? Odor? ________

   b. When was the dispersive electrode package opened? ________________________________________

   c. At the time of removal, was the entire electrode surface in contact with the patient? ___________

   d. Were there separations or discontinuities in the foil substrate? _______________________________

   e. Was the electrode checked for proper placement after patient repositioning or checked at any other time during the procedure? ____________________________________________

   f. Did anyone lean on the dispersive electrode or put tension on the associated cable during the procedure? ________________________________________________________________

   g. If injury occurred beneath the dispersive electrode, was the electrode saved? ________________
11. **ESU Active Electrode**
   a. Where was the active electrode placed when not in use during the procedure? Was it placed in a safety holster? __________________________________________________________________________
   b. Was the active cable draped next to any other cables, leads, or conductive tubing or across the patient? Was it clamped to the drapes? How? ____________________________________________

12. **Hypo/Hyperthermia Units and Radiant Warmers**
   a. Record the following:
      i. Placement of temperature probes (rectal, esophageal, skin) ________________________________________
   ii. Times unit was turned on and off ________________________________________________________________
   iii. Set temperatures and times ________________________________________________________________
   iv. Mode of operation (manual, automatic, warm-up) ________________________________________________
   b. Was the temperature of the unit routinely checked? How? Results? ________________________________
   c. Was the patient’s temperature routinely checked? How? Results? ________________________________
   d. Describe the cleaning/sterilization procedure for the hypo/hyperthermia blanket. ____________________

13. **Blanket and Solution Warming Cabinets**
   a. Were blankets that were warmed in a warming cabinet placed on the patient? Where were they placed? __________________________________________________________________________
   b. Were irrigation solution bags taken from a warming cabinet and placed on or under the patient? Where were they placed? ________________________________________________________________
   c. What was the set temperature on the warming cabinet for both the blanket and the solution chambers? Was it above 110°F? ______________________________________________________________________

14. **Endoscopes and Accessories**
   a. Is there visible damage to or deterioration of the insulation of the electrosurgical handpiece? ______________________________________________________________________
   b. Describe the method of cleaning and sterilization of the endoscope and its accessories. ________________
   c. Is the fiberoptic cable appropriately matched to the light source? ______________________________________________________________________
   d. Are there damaged fibers within the fiberoptic cable? ________________________________________________
   e. Was the fiberoptic cable or endoscope removed while the light source was still powered on? ______________________________________________________________________
   f. Note the placement of the light source and fiberoptic cable in relation to the patient. ______________________________________________________________________
Investigation Questionnaire: Accidental Skin Injury

15. **Pulse Oximeters**
   a. Describe the condition of the pulse oximeter probe and cable. __________________________________________________________
   b. Was the probe used with the correct pulse oximeter? ____________________________
   c. Was the probe moved during the procedure? ____________________________________________

16. **Other Equipment**
   a. Could other equipment have contributed to the problem? Describe. ____________________________
   b. Were difficulties experienced with other devices used? Describe. ____________________________

**F. Summary (Interviewee)**

1. Other comments?
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________
   __________________________________________________________

2. Given your observations, how do you think the injury occurred?
   __________________________________________________________
   __________________________________________________________
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**G. Summary (Interviewer)**

1. Highlight salient points gained from the interview.
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A full bibliography is available upon request; for details, contact the Health Devices Group at healthdevices@ecri.org.

ECRI Citations

The following *Health Devices* articles, listed in reverse chronological order, relate to skin injury in the surgical or intensive care setting:

Preventing burns and fires caused by high-powered light sources [hazard report]. Health Devices 2005 Sep;34(9):325-6.


Citations from Other Publications

The following articles are listed in alphabetical order by author:


Stoll AM, Greene LC. Relationship between pain and tissue damage due to thermal radiation. *J Appl Physiol* 1959 May;14(3):373-82.


Electrosurgical Safety
Conducting a Safety Audit

Summary. ECRI detailed some of the lesser-known risks of electrosurgery in a collection of articles published in the August 2005 Health Devices. However, it’s also important to recognize that even hazards that are well understood by clinical personnel can lead to injury if appropriate safety measures aren’t applied consistently.

In this follow-up to our August 2005 articles, we offer guidance to help healthcare facilities conduct a safety audit that examines critical aspects of the facility’s use of electrosurgical technology. ECRI recommends that healthcare facilities periodically conduct such an audit to ensure that the appropriate equipment and procedures are in place to protect patients and staff from injury. This article reviews some of the key questions to ask during a safety audit, and it includes detailed guidance for developing an electrosurgical safety checklist.
10 Key Questions to Ask during an Electrosurgical Safety Audit

To help healthcare facilities conduct an effective audit, we examine below the critical safety measures that facilities should take to avoid some of the most common electrosurgery-related adverse incidents. While most of these measures are basic, ECRI has found that too often they are misunderstood, forgotten, or ignored. In addition, some users may be unfamiliar with the special risks associated with laparoscopic monopolar electrosurgery and high-current, long-duration activations (e.g., as used for tissue ablation).

The audit might be conducted by members of a safety committee; by clinical engineering, risk management, or surgical staff; or by some combination of personnel from these groups. Periodic reexamination of the issues covered in the safety audit is advised.

1. Are safe practices emphasized in user training and reinforced in daily practice?

The safety of electrosurgery depends largely on clinicians and their adherence to good practices. Ensuring that surgical staff members are properly trained in these practices will significantly improve safety.

Verify that user training covers the following (many of these topics are described in subsequent items):
- The operating principles of electrosurgical units (ESUs), including devices used for argon-enhanced electrosurgery (where relevant)
- The causes of return-electrode-site, active-electrode-site, and alternate-site injuries and the preventive measures that can be taken to minimize associated risks
- Fire safety
- Surgical smoke evacuation
- The unique causes of injuries during laparoscopic electrosurgery and high-current ablation and the preventive measures that can be taken to minimize the risks

2. Have you developed an electrosurgical safety checklist to reinforce safe practices?

Using a checklist will reinforce safe practices by reminding clinical staff of each safety step while they are preparing for or performing electrosurgery. In the next section, Developing an Electrosurgical Safety Checklist, we present a starter list with safety practices that you can use to create a checklist that addresses your facility’s specific needs.

3. Is RECQM technology used to prevent return-electrode-site injuries?

Return-electrode contact-quality monitor (RECQM) technology has proven to be an effective tool for helping to prevent patient burns at the site of the return electrode during most electrosurgical procedures.

Ensure that RECQM capability is provided on all general-purpose ESUs in your inventory. In addition, you should verify that dual-foil return electrodes, which are needed to enable contact-quality monitoring, are available and are being used. (Note that RECQM is unnecessary when large-area capacitive return electrodes are used instead of adhesive return electrodes. For a discussion, refer to the December 2000 Health Devices Evaluation of the Megadyne Mega 2000 Return Electrode.)

4. Are safeguards in place and followed to protect against active-electrode-site injuries?

For all ESUs in your inventory, verify, at minimum, that visual activation indicators illuminate and that audible activation indicators are clearly audible. Also ensure that during surgical procedures, all active electrodes are in safety holsters (see the photos on the bottom of page 419) or otherwise placed safely away from the surgical field and patient when they are not in active use.

5. Are reusable accessories replaced on time?

If your hospital employs reusable cables or active electrodes, ensure that a replacement policy has been established and is followed for these accessories to minimize the risk of failure during use. Internal failure of a cable’s conductor may cause sparking and fires, and employing reusable active electrodes until they fail may result in patient injury (e.g., tonsillectomy burns inside a patient’s mouth).

Because cable and electrode failures are not easily detected by normal inspections, ECRI recommends periodically replacing these reusable accessories. If the equipment manufacturer does not publish a recommended replacement schedule, consider replacing the devices after one year of use.
6. Is surgical smoke evacuated to ensure safety and comfort?

Ensure that a policy is established and followed regarding surgical smoke evacuation. ECRI recommends that, at minimum, surgical smoke be evacuated in the following circumstances: (1) when tissue is being ablated in patients infected with human papillomavirus (HPV), (2) when there is expected to be enough smoke to obscure vision and therefore diminish staff performance, or (3) when smoke causes staff discomfort. For more information, refer to “Should You Evacuate Surgical Smoke?” in the March 2001 *Health Devices*. More detailed discussions can also be found in the following articles: “Technology Management Guide: Clearing the Air—Should Surgical Smoke Be Evacuated?” (*Health Devices* April 1997) and “Should Surgical Smoke Be Evacuated? (Revisited)” (*Health Devices* September 1999).

7. Is equipment standardization used to minimize user error?

Determine your facility’s level of standardization regarding ESUs and accessories, and then consider whether your purchasing practices need to be altered to increase equipment standardization. A lack of standardization increases the chance of error during the use of these devices. If your facility uses multiple product models for the same procedures, provide adequate training to ensure correct use of each model.

8. Are policies in place and followed to prevent surgical fires?

Ensure that safe practices are followed and that preventive measures are implemented to minimize surgical fires. Although surgical fires—fires on or in the surgical patient—are rare, they do occur, and their consequences can be devastating. ECRI’s investigations and research show that electrosurgical equipment is a common ignition source in these fires.

Key preventive measures include minimizing the risks associated with oxygen and nitrous oxide enrichment near the surgical site, especially in head and neck surgery, and not draping the patient until all flammable prepping agents have fully dried. Also, keep a 5 lb carbon dioxide fire extinguisher in every room used for electrosurgery. Refer to the January 2003 *Health Devices* for more information on surgical fire safety. *Health Devices* will publish updated guidance on this topic in 2006.

9. Are policies in place and followed to minimize the special risks during laparoscopic monopolar electrosurgery?

Ensure that policies are in place and followed to minimize the special risks associated with the use of monopolar electrosurgery during minimally invasive procedures, such as laparoscopy. Some of the resulting burns may lead to bowel perforations, which can be fatal.

For instance, during such procedures, electrical current can become concentrated within narrow internal pathways, leading to excessive heating of internal structures. Also, contact between an activated electrode tip and other conductive instruments within the patient can cause those instruments to become energized, possibly leading to a burn.

Consider whether any technology solutions should be used to minimize the risks of stray electrosurgical energy...
Guidance Article

(leakage current) from the shaft of the active electrode passing through gaps in the insulating material or across the intact insulation by means of capacitance to other instruments or internal tissues. ECRI discussed this topic in detail in the August 2005 Health Devices. (See the inset on page 416 for more information.)

10. Are policies in place and followed to minimize the special risks associated with tumor ablation and other high-current ESU procedures?

During high-current, long-duration activations, a single conventional return electrode may be inadequate to safely disperse high currents; consequently, a patient may be burned at the site of the return electrode. Ensure that clinicians are aware of this often unrecognized electrosurgical hazard—which has developed as a result of newer techniques that require the continuous application of high current for a prolonged period of time—and verify that appropriate practices are followed to minimize the associated risks. For example, some generator manufacturers recommend that for high-current procedures, facilities use either multiple return electrodes or return electrodes that are no smaller than a specified size.

A specialty electrosurgical generator may increase the risk of injury if it does not offer RECQM, return-electrode-fault monitoring, or other measures to minimize the possibility of return-electrode-site burns. In addition, the likelihood of overwhelming the return electrode can increase if a conductive solution—such as saline or lactated Ringer’s solution—is used as a distention/irrigation medium. Such solutions can conduct and disperse electrosurgical current away from the surgical site, causing a loss of surgical effect that can lead an operator to increase the power settings of the ESU. Conductive solutions also lower electrical impedance at the active electrode, which further elevates current. ECRI also addressed these topics in the August 2005 issue. (See the inset on page 416.)
Developing an Electrosurgical Safety Checklist

The information presented below can be used as a guide for developing a checklist that clinical staff will employ to ensure that safe practices are followed before, during, and after electrosurgical procedures. This is designed as a starter list; facilities should modify or add to it as appropriate to meet their particular needs.

Preoperative Precautions and Procedures

1. **ESU condition**
   1.1 Examine the electrosurgical unit (ESU) and its accessories for defects. Do not use cables or accessories with damaged (e.g., cracked, burned, taped) insulation or connectors.
   1.2 When the ESU goes through its self-test mode after being powered on, or when it is first activated during surgery, do the following:
      1.2.1 Verify that the audible activation tone is loud enough to be heard over other noises in the operating room.
      1.2.2 Verify that the visual activation indicator illuminates.
   1.3 Before connecting the return electrode, verify that the unit will not activate and that it sounds an alarm if a user attempts to activate the unit while the return electrode is disconnected.
   1.4 Verify operation of any additional alarms or safety features, if applicable.

2. **Return-electrode integrity and application***
   2.1 Clean, shave (if applicable), and dry the application site.
   2.2 If the ESU incorporates a return-electrode contact-quality monitor (RECQM), verify that a dual-foil-surface return electrode is being used to enable contact-quality monitoring. (Note that an RECQM is unnecessary when large-area capacitive return electrodes are used instead of adhesive return electrodes.)
   2.3 Confirm that the electrode’s expiration date has not passed.
   2.4 Before placement, inspect the electrode for any flaws or damage (e.g., discoloration, areas that appear dry, lack of tackiness).
   2.5 Follow the manufacturer’s recommendations for return-electrode application, and ensure that the electrode is firmly attached to the skin.
   2.6 Ensure that the electrode is not applied to a weight-bearing surface (e.g., underneath the patient, on bony prominences).
   2.7 Ensure that no sections of the electrode overlap. In particular, verify that no electrode is applied circumferentially around a small limb because this placement increases the likelihood of an overlap and might cut off circulation.
   2.8 If possible, apply the return electrode so that one of its long edges (one without the cable connection) is positioned closest to the surgical site.

3. **Precautions for patients with a pacemaker or ICD**
   Take appropriate precautions for patients with pacemakers or implantable cardioverter-defibrillators (ICDs). Follow recommendations from the pacemaker or ICD manufacturer or from your facility’s cardiology department. When developing a policy for such patients, consider including the following steps:
   3.1 Use a safer pacing mode (e.g., fixed-rate single-chamber mode), or deactivate the ICD if appropriate.
   3.2 Ensure that the following are readily available: a pacemaker or ICD programmer, external defibrillator, external pacemaker, and cardiac drugs.
   3.3 Ensure that the return electrode is not placed near the pacemaker or ICD.
   3.4 Ensure that the return electrode is not placed so that the pacemaker, ICD, or leads are in the path of the ESU current.

* The items in this section apply specifically to the use of adhesive return electrodes. Although most of these measures (e.g., the use of an RECQM) are not applicable when large-area capacitive return electrodes are used, appropriate measures, such as checking the position and condition of electrodes, should be substituted.
3.5 Ensure that the return- and active-electrode cables are not placed near the pacemaker, ICD, or leads.

4. Safeguarding against alternate-site injuries

4.1 Eliminate patient contact with grounded objects.

4.2 Ensure that the active electrode is properly seated in the electrosurgical handpiece. (See the photos above.)

4.3 If feasible, remove nonvital monitoring electrodes (e.g., esophageal probes, rectal probes) from the patient.

4.4 Keep ECG and other monitoring electrodes as far as possible from the surgical site and from the active- and return-electrode cables.

4.5 If possible, do not use needle electrodes for monitoring or other nonelectrosurgical purposes. Needle electrodes increase the risk of alternate-site burns because stray current can flow through the small contact area of the needle, particularly when monopolar delivery is used. The risk cannot always be avoided by disconnecting the monitoring cable at the monitor end. If using needle electrodes is deemed necessary, avoid using monopolar electrosurgery following needle placement. Instead, consider using a scalpel, a laser, or bipolar electrosurgery.

5. Drying time for prepping agents

Verify that flammable prepping solutions and tinctures (if used) have fully dried before draping the patient or activating the ESU.

6. Use of safety holsters

Position an insulated safety holster (see the photos below) for each active electrode; the safety holsters should be in convenient locations.

7. Sparking the active electrode

Ensure that no one sparks the active electrode to ground or to the return electrode to test the ESU. Under some circumstances, sparking the active electrode this way can create a current path that passes through a point where the patient is touching grounded metal; consequently, the patient may be burned at this point.

Intraoperative Precautions and Procedures

8. Minimizing oxygen buildup

8.1 Minimize the buildup of oxygen and nitrous oxide beneath drapes and, during oropharyngeal surgery, in the oropharynx.

8.2 Verify that electrosurgery is not used around the open tracheobronchial tree.

9. Activation and deactivation

9.1 Activate the unit only when ready to deliver electrosurgical current and only when the active tip is in view. This consideration is especially important when a surgeon is viewing through a microscope or endoscope.

9.2 Allow only the user of the active electrode to activate the device, regardless of the activation mechanism (e.g., footswitch) used.

9.3 Keep the active electrode clean; do not, however, wipe the electrode on drapes.
9.4 Deactivate the unit before the tip leaves the surgical site.

9.5 Place the active electrode in a safety holster when not in use. (See the photos on the bottom of page 419.) When long electrodes (e.g., for endoscopic instruments) are used, store them at a location away from the patient.

10. Power settings
   10.1 Use the lowest possible power settings and minimum activation times necessary to achieve the desired surgical effect at the target-tissue site.
   10.2 When a surgical effect is not evident or is less than expected for the surgical circumstance, look for other problems (e.g., confirm adequate placement of the return electrode, check all cable connections) before increasing the generator’s power setting.

11. Repositioning a patient
   Check contact and adherence of the return electrode each time the patient is repositioned.

12. Patients with a pacemaker or ICD
   12.1 Do not use the active electrode in the immediate vicinity (within approximately 6 in [15 cm]) of a pacemaker, ICD, or the associated leads.
   12.2 When possible, use bipolar electrosurgery or alternative methods (scalpel or laser) for patients with pacemakers or ICDs.
   12.3 If monopolar electrosurgery is needed, to the extent possible use short intermittent bursts of activation, which will allow the heart to be paced between activations in the event of inhibiting interference; these bursts should be at the lowest output level needed to achieve the desired surgical effect.

Documentation and Postoperative Procedures

13. Inspecting the patient
   When removing the return electrode, inspect the patient for injuries at the return-electrode site and at other sites (e.g., the sacral area). In virtually all cases, electrosurgical injuries are immediately visible following a procedure; pressure injuries may not show up for as long as one or two days following surgery, however.

14. Documenting all findings
   Ensure that procedure documentation includes:
   14.1 The ESU identification number
   14.2 The ESU settings used (e.g., monopolar or bipolar, cutting or coagulation)
   14.3 The location of the return electrode
   14.4 The condition of the skin at the return-electrode site before and after the procedure
   14.5 The use and position of any other equipment (e.g., hypo-/hyperthermia units, temperature probes) employed during the procedure, including identification numbers

15. Saving items associated with an incident
   If any problems are noted during or after the procedure, save all disposable items and their packages (e.g., so that expiration dates can be confirmed).
In the past three years, *Health Devices* has published three Evaluations of general-purpose infusion pumps equipped with dose error reduction systems (October 2002, October 2003, and December 2004). In those Evaluations, the Baxter Colleague CX (shown in the photo) and 3CX pumps were rated Acceptable.

Since our 2002 Evaluation, however, we have updated our criteria for dose error reduction systems to reflect the increasingly sophisticated capabilities of such systems.* Unfortunately, the Guardian dose error reduction software provided on the Colleague pumps has not kept up with advances in the technology, and it no longer compares favorably with the systems on other general-purpose pumps. Guardian’s principal drawbacks are these:

- Setting up the drug library in the pump is laborious. Drug names, dose units, concentrations, and dose limits must be entered directly on the pump’s keypad (rather than on a laptop computer)—there is no spreadsheet function for listing and reviewing any of this information.
- The drug library is small, and most of the drugs are pre-assigned by Baxter rather than being programmable by the user, preventing a facility from tailoring the drug library to meet its specific needs.
- The pump does not default to the dose error reduction system on power-up—the user must specifically select this function.
- Drug names cannot be displayed using TALLman lettering (e.g., DoBUTamine, DOPamine).
- There is still no dedicated log for storing (1) programmed doses that trigger alerts or (2) the subsequent programming that activates in response to the alerts by either setting a dose that is within limits or enabling a limit “override.” The lack of such logs makes it impossible to measure the effectiveness of the dose error reduction system and to use logged data to improve clinical practice.

Because these pumps no longer meet many of our dose error reduction criteria, we are changing their rating: They are now rated Not Recommended. This means that, while the pumps’ performance and safety are adequate, and pumps in inventory are still suitable for use, we no longer recommend them for new purchases. There are better choices available.

In addition, while not a direct factor in our rerating of these pumps, the number of recalls and other corrective actions affecting these pumps concerns us.** These recalls, which include two U.S. Food and Drug Administration (FDA) Class I recalls—one in February and one in July—later resulted in FDA’s seizure of Colleague pumps that Baxter intended to use to replace pumps sent to the company for repair. This is a troubling number of problems for pumps that have been around as long as the Colleague pumps have. The impact on users has been extremely burdensome.

It’s not clear what will happen from here. Baxter has not been able to ship Colleague pumps to new accounts since summer 2005. Shipments will not resume until Baxter receives clearance for two FDA 510(k) regulatory filings covering intended fixes for the pumps. One filing was submitted on November 19, 2005; Baxter anticipates submitting the second filing in January 2006.

If Baxter resolves the many reliability issues involving the Colleague pumps and upgrades the capabilities of the Guardian software to keep up with the advances in technology, we will revisit our rating of these pumps.

* These criteria are summarized in a checklist available in the members area of our Web site. Log onto www.ecri.org, go to your membership page, click on the Health Devices Journal option, scroll to the December 2004 issue, click “(Overview),” and click “Infusion Pump Checklist.”

** In the past year alone, the Colleague CX and 3CX have been the subject of 11 Action Items published in Health Devices Alerts, some of them covering more than one problem. See Accession Nos. A6077, A6188, A6216, A6238, A6434, A6520, A6652, A6683, A6703, A6756, and A6943.
Thank You
To All Our Clinical Reviewers

We deeply appreciate the contributions made by the following clinicians and other healthcare professionals, who donated their time and shared their expertise as reviewers of the Evaluations and Guidance Articles published in *Health Devices* during the past year. We would also like to thank the countless others—too numerous to mention here—who have helped us inform the healthcare community about medical-device-related problems through our Problem Reporting System.

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*The end of the year is also a good time for us to thank you, our members, for your support of the Health Devices program. We wish you all a safe and happy New Year.*
Problem Reports

Policy statement. ECRI encourages members, healthcare providers, patients, and suppliers to report all medical-device-related incidents and deficiencies to us so that we can determine whether a report reflects a random failure or one that is likely to recur and cause harm. Reports can be generic or model specific. We add all reports to our internal confidential databases to track trends of device failure or lot-specific defects. Although many reports do not result in a published article, we inform the reporting party of our findings or opinions when appropriate. As soon as we become aware of device hazards and problems, we inform the suppliers and invite them to respond constructively.

If our investigations yield information that should be communicated to the healthcare community, we publish the information in Health Devices as either a Hazard Report or a User Experience Network™ (UEN™) article, depending on the level of risk associated with the problem. Member hospitals may reproduce these reports for internal distribution only. This policy does not apply to other articles in Health Devices, unless otherwise noted.

Submitting a report. Please report problems to us by mailing or faxing one of the problem reporting forms in your Health Devices binder, by sending us a letter, by completing the online form available at www.ecri.org/problemreport, or by calling +1 (610) 825-6000. The identity of the reporting individual or institution is never revealed without permission.

Hazard Report

Using External Defibrillators in Oxygen-Enriched Atmospheres Can Cause Fires

PROBLEM
ECRI continues to receive reports of fires starting when external defibrillators are used with oxygen administration devices (e.g., oxygen masks, manual resuscitators, ventilators), which can create oxygen-enriched areas around a patient’s head, neck, and chest. These fires often spread through surface-fiber flame propagation, in which flames travel across body hairs or fabric fibers, typically toward an oxygen source. In many cases, these fires do not burn skin or underlying fabric; sometimes, however, they can burn people or spread to bedding, clothing, supply tubing, or medical devices, including oxygen administration devices themselves (Bruley and Lavanchy 1989).

DISCUSSION
External defibrillation normally doesn’t create a fire risk, but it may do so when (1) there is an oxygen-enriched atmosphere and (2) an electric arc forms between two conducting sources.

Oxygen administration devices can raise the oxygen concentration around a patient’s head, neck, and chest. The exact concentration depends on factors such as the device’s oxygen flow rate, the position and direction of the oxygen outflow, the amount of time oxygen has been flowing, the position of the patient, and the movement of nearby people and equipment. In most cases, the area will extend less than 30 cm (12 in)
any direction from the outflow point, and the concentration will quickly return to ambient levels when the source of enrichment is turned off or removed.

An electric arc in an oxygen-enriched atmosphere can ignite body hairs or the surface nap fibers on most fabrics. Two of the common ways these fires can occur during defibrillation are when a paddle or defibrillation electrode is placed close to an ECG electrode, or when there is poor contact between a patient’s skin and the defibrillator paddles or disposable defibrillation electrodes being used. Poor contact can be caused by any of the following:

- Insufficient force during paddle application.
- Use of the wrong amount or wrong type of gel (e.g., ultrasound gel); or, when gel pads are used instead, use of pads that are the wrong size or that have passed their expiration date.
- Application of paddles or defibrillation electrodes on irregular surfaces (e.g., bony prominences, wires, ECG electrodes).
- Misapplication of paddles (e.g., the metal surface of the paddle is not completely on the conductive pad).
- Improper patient surface preparation (e.g., not shaving areas where paddles or electrodes will be applied).
- Use of defective disposable defibrillation electrodes (e.g., a fold in the electrode, an expired electrode, a dry electrode).

ECRI has discussed this problem in *Health Devices* several times (December 1979, March-April 1987, July 1994). Also, the medical literature includes numerous references to this hazard, starting as early as 1972. Furthermore, the American Heart Association recently proposed updating the defibrillation guidelines it offers to healthcare providers to include a description of this problem. However, despite widespread awareness, fires during defibrillation in oxygen-enriched atmospheres continue to occur.

**RECOMMENDATIONS**

1. Alert clinicians to the problem and to this report. This danger must be periodically reemphasized so that it will not be ignored or forgotten.
2. If possible, remove all sources of supplemental oxygen from the area around the patient before defibrillation. This includes all manual and gas-powered resuscitators, breathing circuits, masks, and nasal cannulae that provide oxygen at concentrations above 21% (i.e., above normal ambient concentration).

   If it isn’t possible to remove such oxygen sources, they should be turned off a few seconds before defibrillation to reduce the localized oxygen concentration. As an added precaution, oxygen sources shouldn’t be placed on a bed or patient, and they shouldn’t be draped over a siderail, because a clinician could forget to turn off the device or the device could leak oxygen.

3. To reduce the risk of arcing during defibrillation:
   A. If defibrillator paddles are used:
      — Apply the defibrillator paddles firmly, and ensure that there is unobstructed, even contact with the patient’s skin.
      — Do not place defibrillator paddles on an ECG electrode or wire.
      — When gel pads are used in place of conducting gel, use pads that are larger than the metal surface of the paddle; that have not reached their expiration date; and that are sticky, flexible, and wet.

   B. If disposable defibrillation electrodes are used:
      — Ensure that the electrodes have not reached their expiration date and that they are sticky, flexible, and wet.
      — Ensure that electrodes properly adhere to the patient and are flat against the skin. Do not place pads over bony prominences, excessively hairy areas, electrode leads, or wires.
      — Do not place the electrodes on an ECG electrode or wire.
4. Ensure that defibrillation protocols include steps, such as those above, to reduce the risk of arcing in an oxygen-enriched atmosphere. However, preventive measures must not interfere with resuscitation attempts.

Reference


**Suppliers.** These devices are available from a variety of sources; consult ECRI’s *Health Devices Sourcebook* or Health Devices International Sourcebase for suppliers. •

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**Talk to the Specialist**

**Ventilator Gas Supply Inlet Filters**

**Question.** Should a ventilator’s gas supply inlets have filters?

**Answer.** Yes. Most ventilators have a particulate filter, which is encased in a water trap, on both the air and the oxygen inlet. (On some ventilator models, the oxygen filter and trap are inside the unit.) Although medical gas systems are supposed to be constructed—and tanks are supposed to be filled—so that no water or particles enter the gas, ECRI has seen numerous systems in which this problem occurred. These contaminants can damage ventilators by corroding metal and clogging small passages, and they can also harm patients. Filters reduce the likelihood of these problems and are therefore important to use; note, however, that they cannot prevent all risks because they do not trap very small particles.*

Inlet filters need to be checked regularly to improve patient safety, protect ventilators, and identify any problems with the medical gas system. (For example, the presence of green particles in the filters or traps would indicate that copper pipes in the gas system might be corroding.) If the filters or water traps contain particles or water, then the entire system needs to be inspected and its problems fixed.

**UMDNS terms.** Filters, Gas [15-649] • Ventilators, Intensive Care [17-429] •

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Cracks have formed on the U-brackets of our Medcare Total Support Lifts. The U-bracket is welded to the top of the device’s mast, attaching the boom to the mast. In each case, the cracks were noticed after a patient was lifted; we later learned that this resulted from operators trying to maneuver the lift by pushing the boom instead of the handlebar, which is located at the backend of the lift. Although no injuries occurred, we believe that if the problem goes unnoticed, it could lead to patient or staff injuries. Medcare said it will replace the U-brackets at no cost under warranty, perform an in-service training session for our operators, and send us warning stickers to be placed on the side of the boom.

**SUPPLIER’S CORRECTIVE ACTION**

Medcare is aware of the problem. In October 2002, the company doubled the U-bracket’s thickness to make it less prone to cracking, bending, and twisting. Despite this change, the company strongly encourages users to maneuver the lift only from its backend, using the handlebar (Figure 2a), because other ways of maneuvering the lift can still damage the U-bracket if enough force is applied. Although Medcare didn’t initiate a recall, it is now proactively inspecting all known units in the field and providing in-service training.

An explicit warning against improperly maneuvering the device is not included in the current version of the operator’s manual, but Medcare is incorporating such a statement into the manual’s next edition. The company also freely provides labels—to be affixed to the boom—that warn users against improperly operating its lifts.

**RECOMMENDATIONS**

1. Visually inspect all Medcare 400001 and 400003 lifts to identify any cracking, bending, or twisting of the U-bracket (see Figure 1 for identification of the U-bracket). If damage is found, remove the unit from

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**ECRI’s User Experience Network**

User Experience Network™ (UEN™) articles describe problems that ECRI believes are unlikely to pose a significant risk of harm. Most describe common or nuisance problems that can be corrected with an available modification or revised operating or maintenance procedures. Typically, they include the hospital’s report and ECRI’s comment. When appropriate, they also include the supplier’s response and recommendations for corrective action.
service until a new U-bracket has been installed and a warning label has been affixed. The U-bracket will be replaced at no charge if the device is still under warranty (i.e., within five years of the purchase date). The warning labels are available free of charge regardless of the warranty status. If the part is not under warranty and there are no signs of damage, routinely monitor the U-bracket for problems and replace the part only if damage is visible.

2. Ensure that the visual inspection described in Recommendation 1 is included in your inspection and preventive maintenance procedure. This inspection should be performed at least annually.

3. Train clinicians to maneuver the lift only from the unit’s backend, using the handlebar, and make them aware of the consequences of maneuvering the device incorrectly. (Contact Medcare to obtain training videos or to schedule an in-service session.) Document which users receive the training, and repeat training periodically.

**UMDNS term.** Lifts, Patient Transfer [12-330]

**Supplier.** Medcare Products [370363], Burnsville, Minnesota (USA); +1 (800) 695-4479, +1 (952) 894-7076; www.medcarelifts.com

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**Figure 2a.** Correct operation

**Figure 2b.** Incorrect—Do not push or pull the boom

**Figure 2c.** Incorrect—Do not push the patient
Health Devices System

Objectives

To improve the effectiveness, safety, and economy of health services by:

1. Providing independent, objective judgment for selecting, purchasing, managing, and using medical devices, equipment, and systems.

2. Functioning as an information clearing-house for hazards and deficiencies in medical devices.

3. Encouraging the improvement of medical devices through an informed marketplace.