HealthStream Regulatory Script

Medical Equipment Safety

Version: September 2006

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Lesson 3: Hospital Beds
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Lesson 1: **Introduction**

<table>
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<tr>
<th>Introduction</th>
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<tbody>
<tr>
<td>Welcome to the introductory lesson on medical equipment safety.</td>
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<tr>
<td>The Institute of Medicine (IOM) estimates that medical devices cause serious injury to 1.3 million Americans each year.</td>
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<tr>
<td>With proper systems in place, many of these injuries can be prevented.</td>
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</tbody>
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As your partner, HealthStream strives to provide its customers with excellence in regulatory learning solutions. As new guidelines are continually issued by regulatory agencies, we work to update courses, as needed, in a timely manner. Since responsibility for complying with new guidelines remains with your organization, HealthStream encourages you to routinely check all relevant regulatory agencies directly for the latest updates for clinical/organizational guidelines.

*If you have concerns about any aspect of the safety or quality of patient care in your organization, be aware that you may report these concerns directly to JCAHO.*
Course Rationale

This course will help you:
- Use medical devices safely.
- Protect your patients from medical device risks.

You will learn about:
- General medical device risks and safety
- Specific risks and safety for selected medical devices
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<th>Course Goals</th>
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<tr>
<td>After completing this course, you should be able to:</td>
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<tr>
<td>• Recognize factors that contribute to medical device risks.</td>
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<td>• Identify JCAHO [glossary] and FDA [glossary] contributions to medical device safety.</td>
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<tr>
<td>• List the risks of selected medical devices.</td>
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<tr>
<td>• Identify strategies for addressing each risk.</td>
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Course Outline

This introductory lesson gives the course rationale, goals, and outline.

Lesson 2 gives an overview of medical device safety. This includes factors that contribute to device risk. It also includes general strategies for addressing risks.

Lesson 3 focuses on safety with hospital beds.

Lesson 4 covers the risks and best practices for safety with glutaraldehyde and ethylene oxide.

Lesson 5 addresses infusion pump risks and safety.

Lesson 6 discusses the risk of electrosurgical burns and how to guard against burns.

Lesson 7 covers risks and precautions with lasers.

Finally, lesson 8 addresses single-use devices.
Lesson 2: Equipment Safety Basics

**Introduction & Objectives**

Welcome to the lesson on safety basics.

After completing this lesson, you should be able to:

- Define "medical device."
- List factors that contribute to medical device risks.
- Identify the parts of an equipment management program.
- Recognize the FDA criteria for a well-designed device.
- List best practices for users to help reduce medical device risks.

[FLASH ANIMATION: 2001.SWF/FLA]
What Is a Medical Device?

A medical device is any item used to diagnose, treat, or prevent:
- Disease
- Injury
- Other medical conditions

Medical devices do not include:
- Drugs
- Biologics
- Food
Risks of Medical Devices

Risks of medical devices fall into the following general categories:
- Chemical
- Mechanical
- Thermal
- Electrical
- Radiation
- Biological

These risks can be the result of:
- Clinical problems
- Device problems
- User problems

Let’s look at each type of problem in turn.
Clinical Problems

Clinical problems are risks that can come up with any medical treatment.

These problems include:
- Patient allergy or sensitivity
- Infection
- Events that have to do with how the device interacts with the patient’s pre-existing medical conditions
Device Problems

Device problems are:
- Device failure
- Device malfunction

Device problems can happen due to:
- Design defects
- Development defects
- Poor manufacturing quality
- Material problems
- Mechanical malfunction
- Electrical malfunction
- Software malfunction
User Problems

User problems happen because of the way a user interacts with a device.

User problems can happen because of:
- Poor device labeling
- Confusing device instructions
- Poor device packaging
- Poor user training
- Limitations of the user (e.g., physical or mental limitations)
- Use of the device in ways the manufacturer did not expect or adequately control for
- Use of the device in an environment that affects user abilities and/or device operation
- A use for the device that does not match what the user would expect
- Poor device maintenance
As you can see, many problems can come up with medical devices. For this reason, JCAHO requires facilities to have an equipment management program.

The goals of the program are to:
- Ensure that medical devices are available, safe, and effective
- Minimize the risks of medical equipment
An equipment management program should have four parts:
- **Equipment selection**
- **Equipment maintenance**
- **Equipment evaluation**
- **Orientation and training**

Click on each to learn more.

### Equipment selection
Facilities should have criteria for choosing equipment. They should look at:
- Equipment functionality
- Possible physical risks
- Incident history (if any)

### Equipment maintenance
Equipment should be inspected, tested, and serviced on a regular schedule.

### Equipment evaluation
Equipment should be evaluated periodically. This evaluation should look at:
- The reasons for using the equipment
- The scope of use for the equipment
- Equipment performance
- Equipment effectiveness

### Orientation & training
Clinicians, patients, and families must be:
- Trained on how to use medical devices, or
- Oriented to the equipment used in their care.
JCAHO also requires facilities to have procedures for:
- Monitoring and acting on equipment / supply hazard notices and recalls
- Monitoring and reporting device incidents, as required by the Safe Medical Devices Act of 1990 (link to glossary)
- Reporting and investigating problems, failures, and user errors with equipment and supplies
Another aid to minimizing device hazards comes from the FDA:

- The FDA has design guidelines.
- These guidelines ask manufacturers to consider the needs of both users and patients when designing equipment for safety.
Device Design

According to the FDA, a well-designed device must:

• Be consistent with the experience of the user.
• Be logical, and not confusing.
• Minimize the need for the user to do mental math or rely on memory.
• Not expect the user to have exceptional strength, dexterity [glossary], vision, and/or hearing.
• Alert the user to device-related problems.
• Prevent the user from making fatal errors.
• Have readable and understandable labeling.

Devices that you use should meet these guidelines.
Finally, certain **best practices** can help the user avoid problems:

- Read and understand all instructions and labeling before using a device.
- Know the patient populations for which the device is indicated and/or contraindicated.
- Inspect or test equipment before use.
- Keep devices properly maintained and serviced.
- Do not use devices that have malfunctioned.
- Do not use devices that have passed their shelf life or expiration date for sterility.
Safe medical equipment meets the needs of:

- a. JCAHO and OSHA
- b. The user and the patient
- c. The manufacturer and the FDA
- d. The attending physician and the charge nurse

**MULTIPLE CHOICE INTERACTION**

Correct: B

A, C, and D: Incorrect. The correct answer is B.

B: Correct.
Summary

You have completed the lesson on equipment safety basics.

Remember:
- Medical devices can have risks.
- These risks are due to clinical problems, device problems, or user problems.
- JCAHO requires healthcare facilities to have equipment management programs.
- A safe device meets the needs of the user and the patient.
- To help minimize device hazards: 1) Read and understand all instructions. 2) Inspect or test all devices before using. 3) Keep equipment properly maintained and serviced.

The rest of the course highlights some of the risks with selected types of devices.

Keep in mind that this course provides an overview only.

Check with your supervisor for specific information about device safety in your facility.
### Introduction & Objectives

Welcome to the lesson on hospital bed safety.

After completing this lesson, you should be able to:
- Identify electric bed risks.
- List strategies to address electric bed risks.
- Recognize the risks of special care beds and how to address these risks.
- Recognize the risk of entrapment with bed rails.
- List strategies to address bed rail risks.

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<td>Psychiatric risks &amp; safety</td>
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<td>Examples</td>
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<td>Patient risks &amp; safety</td>
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<td>Safety</td>
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<th>Bed Rails</th>
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<td>Risk of entrapment &amp; suffocation</td>
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<td>Safety</td>
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Overview & Risks

Hospital beds are involved in many patient accidents.

Problems may happen with:
- Electric beds
- Special care beds / tables
- Bed rails

Let’s take a closer look at each.
Electric Beds & Pediatric Patients

Electric beds are common in healthcare facilities.

For pediatric patients, electric beds can be a hazard.

Pedestal-style electric beds with walk-away down controls (link to glossary) are especially dangerous.

Pediatric patients may be fatally crushed beneath these beds if they accidentally activate the down control when playing around the bed.
To help prevent pediatric tragedies with electric beds:

- Disable walk-away down on all pedestal-style electric beds. Walk-away down is safe on four-poster beds. It is also safe on newer beds with tamper-resistant controls.
- Children under the age of six should not be placed in electric beds.
- Place pediatric patients six years and older in:
  - Non-electric beds,
  - Four-poster electric beds, or
  - Pedestal-style electric beds with momentary (link to glossary) (not walk-away down) controls.
### Electric Beds & Pediatric Patients

Also to help prevent pediatric tragedies with electric beds:

- In pediatric wards and rooms with pediatric patients, keep empty beds in the lowest position. (To discourage visitors from sitting on clean linens, raise the side rails.)
- Use the lockout switch on the nurse control panel to lock out the patient control for bed height on **all** beds (occupied and empty).
Unplugging Electric Beds

If the steps described on the previous screens are taken, it should not be necessary to unplug electric beds in pediatric areas.

Potential problems with unplugging electric beds are:

- Physical strain to staff, if staff members must pull the bed away from the wall and plug it in for each adjustment.
- Delay in emergency treatment if the bed must be raised or lowered before giving treatment.
- Increased risk of damage to bed cord and plug.
Electric beds give suicidal patients a potential cord for hanging.

To help keep psychiatric patients safe:
- Electric beds should not be placed in psychiatric wards.
- Existing electric beds should be replaced. If replacement is not possible, beds should be moved to their lowest flat position. Line cords should be removed.
- In psychiatric intensive care units, electric beds may be necessary. In this case, patient controls should be locked out at the nursing control box. Patients should be monitored carefully.
Fires are another risk with electrical beds.

To help prevent fires involving electric beds, clinical staff should take the following steps:

- Use only a power cord that meets the requirements of the bed manufacturer.
- Plug the power cord directly into a wall outlet. Do not use an extension cord or power strip.
- Make sure the plug and outlet fit together safely and securely. The outlet should be in good working order.
- Make sure the power cord is not damaged (stretched, cracked, etc.).
- Do not cover the power cord with a rug.
- Check all parts of the bed and the floor under and near the bed for dust and lint.
- Test the bed to be sure that it moves freely.
- Test the bed’s control panels to be sure that the bed is in good working order.
- Check the control panels to be sure the covering is not cracked or damaged.
- Check other electrical equipment in the patient’s room for overheating or damage. Be sure the bedclothes and bedding cannot come into contact with power supplies for other equipment.
- Report any problems seen with bed controls or motors.
To help prevent fires involving electric beds, maintenance staff should take the following steps:

- Perform electrical safety testing according to your facility’s protocols.
- Check all electrical outlets to be sure they are clean, intact, and functional.
- Check power cords to be sure they are in good condition. Make sure that plugs are heavy duty or hospital-grade and that they are intact.
- Check battery-powered beds for hot spots in their wiring and battery system.
- Check, maintain, and service bed motors per manufacturer recommendations.
- Check all gas and liquid fittings to be sure they are in good condition.
- Check all switch-type circuit breakers to be sure they move freely.
- Check that the ratings of external fuses match bed requirements.
- Check beds for 120-volt AC powered controls. Replace or convert these to a low voltage AC control.
Special Care Beds and Tables

Special care beds and tables include:
- Rocking beds
- Turning frames
- Circle beds
- Air-fluidized flotation therapy beds
- Low-air-loss flotation therapy beds

IMAGE: 3008.JPG
Special Care Beds and Tables: Risks

Special care beds are complex. This increases the risk of failure and user error.

Risk factors include:
- Special care beds have a wide range of positions and adjustments.
- Accessories are frequently used.
- The support mechanisms and fasteners for these beds must be stable and secure.
- Rocking beds physically shift patients from side to side.

![IMAGE: 3008.JPG]
### Special Care Beds: Patient Population

Incidents involving special care beds often result in severe injuries. This is due to the patient population.

Patients in special care beds may be recovering from:
- Multiple fractures
- Spinal or cranial injuries
- Extensive burns
- Decubitus ulcers (i.e., pressure sores)
- Neurosurgery

For these patients, even a jolt can cause serious injury.
In short, extra caution must be taken with special care beds. These beds must be used properly. Find and read your unit’s procedure manuals on how to safely operate special care beds.
Bed rails can be a cause of patient death.

In a JCAHO study of this issue, patients suffocated due to the following scenarios:

- The mattress and side rail trapped the patient.
- The headboard and side rail trapped the patient’s head.
- The bars of a side rail trapped the patient’s head.
- The side rails trapped the patient, and the patient was wearing a vest restraint. In this case, the restraint strangled the trapped patient.
In the JCAHO study, bed rails involved in patient deaths included:
- Upper rails only
- Upper and lower rails
- Both upper rails and one lower rail
- Continuous full-length rails

In other words, there is a risk of entrapment and death with many types of rails.
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<thead>
<tr>
<th>Bed Rails: Reducing the Risk</th>
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<tbody>
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</tbody>
</table>
To help prevent adverse events with bed rails:
- Staff must be trained in the use of bed rails
- Staff must be educated on the dangers of entrapment.
- Patients and their families also must be educated.
## Bed Rails: Reducing the Risk

Other practices that can address the risk of bed rails are:

- Use bed rail protector pads.
- Test beds for gaps that pose a risk of entrapment. No gap should be large enough to pose a safety risk.
- Use bed rail netting or clear padding to fill gaps and openings. This fills gaps without blocking the view of the patient.
- Position the mattress on the bed with Velcro or anti-skid mats. This prevents the mattress from shifting to one side and creating a gap.
- Lower beds and remove side rails.

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**For more information on testing beds for entrapment risk:**

http://www.fda.gov/cdrh/beds/guidance/1537.html
FLASH INTERACTION: 3016.SWF/FLA

Drag and drop listed items to their proper place in the chart.

<table>
<thead>
<tr>
<th>Bed / Bed Accessory</th>
<th>Risk</th>
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<tbody>
<tr>
<td>Electric Bed</td>
<td>Fatal crushing of pediatric patients</td>
</tr>
<tr>
<td>Special Care Bed</td>
<td>Any unintended movement of patient across or off the bed</td>
</tr>
<tr>
<td>Bed Rails</td>
<td>Patient entrapment and death by suffocation</td>
</tr>
</tbody>
</table>
Summary

You have completed the lesson on hospital bed safety.

Remember:
- Maintain a safe environment for pediatric patients when electric beds are present.
- Avoid the use of electric beds in psychiatric wards.
- Take steps to avoid fires involving electric beds.
- Use and maintain special care beds properly.
- Take steps to prevent bed rail entrapment.
Lesson 4: Glutaraldehyde and Ethylene Oxide

4001

Introduction & Objectives

Welcome to the lesson on glutaraldehyde and ethylene oxide (EtO).

After completing this lesson, you should be able to:

• Identify how and why glutaraldehyde and EtO are used in healthcare.
• List the effects of glutaraldehyde exposure.
• Recognize methods for reducing and preventing exposure.
• List the effects of EtO exposure.
• Recognize methods for reducing and preventing exposure.

FLASH ANIMATION: 4001.SWF/FLA
Overview & Risks

Glutaraldehyde is used as a high-level disinfectant [glossary] and sterilant [glossary].

Ethylene oxide is also used to sterilize heat-sensitive instruments.

Disinfection and sterilization of equipment are critical in healthcare.

However, glutaraldehyde and EtO are toxins that can put healthcare workers at risk.
Glutaraldehyde is a very good disinfectant. It is widely used in healthcare.

Exposure to glutaraldehyde fumes can cause the following short-term effects:
- Eye irritation
- Skin burns
- Coughing
- Wheezing
- Nausea
- Headaches
- Drowsiness
- Nosebleeds
- Dizziness

With long-term exposure, some people become more sensitive to glutaraldehyde. These people develop strong reactions, including:
- Asthma attacks
- Allergic reaction (skin rashes and severe itching)
Glutaraldehyde: Reducing the Risk

OSHA recommends the following to limit worker exposure to glutaraldehyde:
- The room where glutaraldehyde is used should be well ventilated.
- Use the minimum amount of glutaraldehyde needed.
- Store glutaraldehyde in tightly closed containers in a well ventilated area.
- Use "soaking stations" for glutaraldehyde treatment. These stations have an enclosed area to hold trays. Fumes are vented off.
More OSHA recommendations are:

- Use proper PPE [glossary] when working with glutaraldehyde. This includes appropriate gloves, lab coat / apron / gown, and goggles or a face shield. A personal respirator also should be used if the exposure level will be greater than 0.05 ppm.
- Eye wash stations should be available.
- Do not eat, drink, or smoke where glutaraldehyde is used or stored.
- Do not dry-sweep pure glutaraldehyde. Use a vacuum or wet mopping method.
Glutaraldehyde

The final OSHA recommendation is to use an alternative to glutaraldehyde if possible.

Most glutaraldehyde disinfectants:
• Contain approximately 2% glutaraldehyde.
• Take 20 minutes to disinfect equipment (ten hours to sterilize).

Non-glutaraldehyde disinfectants:
• Work about as fast.
• Give similar results.
Disadvantages of non-glutaraldehyde disinfectants are:

- Many contain peracetic acid, hydrogen peroxide, and/or phosphoric acid. All of these can damage the skin and eyes. PPE should be used to minimize risk of exposure.
- Non-glutaraldehyde disinfectants can harm metal devices. Brass is especially problematic.
- Some manufacturers recommend glutaraldehyde disinfection only. They may not honor their product warranty if non-glutaraldehyde disinfectants are used.
Ethylene Oxide: Risks

EtO is used in many healthcare facilities to sterilize heat-sensitive supplies.

EtO is a carcinogen [glossary].

EtO can also cause:
- Genetic damage
- Miscarriage
- Eye irritation and tissue death
- Skin irritation and tissue death
- Burns
- Nausea
- Vomiting
- Diarrhea
- Pulmonary edema [glossary]
- Muscle weakness
- Problems with thinking and memory
- Nerve damage
- Death
Workers may be exposed to EtO as a result of:
- Poor ventilation
- Improper handling or storage of sterilized items
- Poor training of workers
- Not using sterilization equipment properly
- Poor design of the sterilization area
- Sterilization equipment malfunction or leak
To minimize worker exposure to EtO, other sterilization processes should be used whenever possible.

Other options include:
- Steam sterilization
- Ultraviolet irradiation
EtO: Reducing the Risk

If EtO must be used:
- Repair or replace any malfunctioning equipment.
- When changing EtO cylinders, wear coveralls, gloves, goggles, and a respirator.
- Ventilate sterilizers and the sterilization area properly.
- Use gloves and forceps / tongs to remove items from sterilizers.
- Never smoke around EtO.
- Wash skin immediately if it comes in contact with EtO.
- Remove clothes immediately if they are contaminated by EtO.
- Fire extinguishers and emergency showers should be available in areas where EtO is used.

**IMPORTANT!**

OSHA has a specific standard for EtO.

Some of the important points of the standard are highlighted here.

**Review**

True or False: The best way to prevent EtO exposure is to use another method for sterilizing instruments.

a. True  
b. False

**TRUE / FALSE INTERACTION**

Correct: A

A: Correct. This statement is true.

B: Incorrect. This statement is true.
<table>
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<tr>
<th>Summary</th>
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</table>

You have completed the lesson on glutaraldehyde and EtO.

Remember:
- Glutaraldehyde exposure has short-term and long-term toxicity.
- OSHA has many recommendations for limiting exposure to glutaraldehyde. Know and use these.
- EtO is a highly toxic chemical.
- Take appropriate steps to minimize exposure to EtO.
Lesson 5: Infusion Pumps

Introduction & Objectives

Welcome to the lesson on infusion pumps.

After completing this lesson, you should be able to:
- List infusion pump risks.
- Recognize strategies for reducing each risk.
Overview & Risks

An infusion pump may be used to give:
- IV drugs
- IV fluids
- Blood products

Risks of infusion pumps have to do with:
- Infiltration
- Time-to-alarm
- Occlusion [glossary] release bolus [glossary]
- Free-flow
- Air emboli
- Air-in-line detection
- Tampering
- Device failure

Let’s take a closer look at each.
### Risks: Infiltration

Infiltration also may be called tissuing or extravasation.

This occurs when
- The infusion catheter or needle is not inserted properly, or
- The catheter or needle is dislodged during infusion.

As a result, the infusion is not delivered to the bloodstream. Instead, fluid accumulates in the tissue around the infusion site.

This can result in:
- Death of the tissue
- Risk to the patient because of not receiving needed drugs or fluid
In some cases, infiltration may cause the pump to alarm. This can happen if the infiltration leads to a buildup of pressure in the line.

In general, pumps are not designed to alarm for infiltration.

To prevent infiltration:
- Use the smallest catheter possible.
- Choose the largest vein possible.
- Secure the IV site.
- Check the infusion site frequently
- Listen to any patient complaints of pain or discomfort at the site.
Risks: Time-to-Alarm

**Time-to-alarm** means how long it takes for the pump to alarm, after a problem has developed.

An example is the occlusion alarm.

An occlusion is a blockage in flow.

Time can pass before a pump alarms a blockage. The amount of time depends on both the flow rate and the pressure limit set for the occlusion alarm:

- Lower flow rates give longer response times.
- Higher pressure limits give longer response times.

During the time-to-alarm, the patient does not receive needed fluids or drugs.
To reduce the risks related to time-to-alarm, optimize alarm settings for each clinical situation.

Optimum settings will:
- Minimize nuisance alarms.
- Alarm promptly for problems that need your attention.
**Risks: Occlusion Release Bolus**

**Occlusion release bolus** happens when an occlusion is cleared, and this causes the delivery of a bolus dose.

To reduce the risk of bolus infusion, relieve pressure in the line before resolving an occlusion.

Do so by disconnecting the system above the occlusion, if possible.

![Image: Always take appropriate steps to clear occlusions safely!](5007.GIF)
Risks: Free Flow

Free flow happens when there is an uncontrolled infusion from an infusion pump.

Free flow becomes a risk when:
- The infusion pump is more than 12 inches above the patient's heart
- The roller clamp is open

In this case, free flow is likely to happen if:
- The tubing, syringe, or cassette is not placed carefully in the pump housing.
- The pump is opened or the syringe is removed from its clamp.
- There is a break or leak in the upper part of the fluid pathway or the syringe.

Free flow can cause an overdose.
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<th>Free Flow: Reducing the Risk</th>
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<tr>
<td>To prevent free-flow, use only pumps with set-based free-flow protection.</td>
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</table>
Risks: Air Emboli

**Venous air emboli** can be fatal.

Causes of air emboli include:
- Loose connections
- Improper priming of infusion tubing
- Not properly spiking fluids bags and removing air prior to infusion
- Not clamping the catheter when the tubing or injection cap is changed
Infusion pumps must have **air-in-line detection**, to help protect against venous air emboli.

However, false alarms can happen if:
- Tubing is not pushed firmly into the air-in-line detector.
- Any small particles are present on the tubing.
- The infusion is frothy.

In some cases, false alarms are just a nuisance.

When giving certain drugs, false alarms can be dangerous.
To help prevent both air emboli and false air-in-line alarms:

- Clamp catheter when not in use.
- Clamp catheter during tubing and injection cap changes.
- Use air filters.
- Purge all air from tubing and syringes before use.
- Spike fluid bags and remove air prior to infusing.
- Use luer-lock (glossary) connectors.
- Change containers before they run dry.
### Risks: Tampering

Patients and visitors can tamper with infusion devices by:
- Opening pump doors
- Removing syringes and/or administration sets
- Changing settings
- Switching off pumps

Some types of tampering are very difficult to prevent.

To reduce the risk of tampering:
- Lock out programming controls.
- Warn patients of the hazards of tampering.

Consult your facility for additional methods of dealing with patients who tamper with equipment.
Infusion pump failure is rare, unless the device has been dropped or damaged.

To guard against using a damaged pump, check each pump before use. Make sure that:
- The pump is in good working order.
- The pump is up-to-date on its maintenance and service.
- The pump has no signs of damage or dropping.
A best practice to reduce the risk of infiltration is:
- Clamp catheter when not in use.
- Purge all of the air from the tubing.
- Use only pumps with set-based free-flow protection.
- Use the smallest catheter in the largest vein possible.

**MULTIPLE CHOICE INTERACTION**

Correct: D

A, B, C: Incorrect. The correct answer is D.

D: Correct.
You have completed the lesson on infusion pumps.

Remember:
- Infusion pumps are useful devices. However, they do have risks.
- Take steps to guard against these risks.
Welcome to the lesson on **electrosurgical units** (link to glossary) (ESUs).

After completing this lesson, you should be able to:
- Identify the three burn risks with ESUs.
- List strategies for reducing the risk of each type of burn.
### Overview & Risks

Electrosurgery is very common today. In electrosurgery, a generator supplies electric current to:
- Destroy tissue.
- Cut tissue.
- Control bleeding.

Risks with electrosurgery are:
- Burns
- Surgical fires

Surgical fires are covered in another module. Here we will focus on the risk of burns.

User error is the most common cause of electrosurgical burns.
Burns from an active electrode (glossary) can happen if:
- The surgeon places the electrode on the patient between uses, and
- The electrode is switched on accidentally, or the device malfunctions and activates the electrode.
Burns can also happen at the return electrode [glossary].

These burns are often detected after the surgeon tries to use the active electrode several times with no apparent effect.

This usually indicates poor electrical contact between the return electrode and the patient.
Return Electrode Burns

Poor electrical contact between the patient and the return electrode may be due to:
- Poor electrode placement (i.e., placement over fatty tissue, or placement on tissue directly over bone)
- Defective materials on the electrode
- Dried-out conductive gel or adhesive on the electrode
- Inadequate site preparation (e.g., not shaving the skin before placing the electrode)

Poor electrical contact causes strong current between the return electrode and the patient’s skin, when the ESU is activated.

This strong current burns the patient.
The final type of burn that can happen with electrosurgery is an alternate site burn.

Normally, current flows:
- From the generator
- Through the active electrode
- Through the patient
- Through the return electrode
- Back to the generator

However, current will take a shorter, easier path if it can.

If possible, current will leave the patient through something other than the return electrode. For example, it might leave through an EKG lead.

In other cases, a surgical team member might provide an easier path for the current.

When this happens, the patient or clinician will be shocked or burned.
Active Electrode Burns: Reducing the Risk

To help prevent active electrode burns:
- Use only ESUs with audible activation tones. The tone alerts the surgeon if the active electrode is energized accidentally.
- Between uses, place active electrodes in a safety holster, instrument tray, or Mayo stand. Do **not** rest active electrodes on the patient or the surgical drapes.
## Return Electrode Burns: Reducing the Risk

To help prevent return electrode burns:

- Choose a proper site for the return electrode. The site should be flat and muscular. It should be close to the surgical site. It should not bear weight during the procedure. It should not be an area that is likely to get wet during the procedure.
- Prepare the return electrode site before placing the electrode. The site should be cleaned and dried. It should be shaved if hairy.
- Check the return electrode for defects. Look for dried-out conductive gel. Also look for inadequate amounts of gel or adhesive.
- After applying the return electrode, run a hand over the pad to confirm uniform placement. Move your hand from the outside to the inside of the pad. This will ensure that you do not displace any gel.
- Check the return electrode site promptly if ESU activation fails to produce the desired surgical effect.
Alternate Site Burns: Reducing the Risk

To help prevent alternate site burns:
- Use an ESU system that has an electrically isolated [glossary] generator. Avoid generators that are ground-referenced [glossary].
- Use only ESUs that are up-to-date on their routine maintenance and service.
An alternate site burn happens during electrosurgery when:

- An electrically isolated generator is used.  
- The return electrode is placed over muscular tissue.  
- Current leaves the patient through a pathway other than the return electrode.  
- The active electrode is accidentally switched on while in contact with the patient.

**MULTIPLE CHOICE INTERACTION**

Correct: C

A, B, D: Incorrect. The correct answer is C.

C: Correct.
Summary

You have completed the lesson on electrosurgery.

Remember:
• Electrosurgery burn risks include active electrode burns, return electrode burns, and alternate site burns.
• Take steps to prevent each of these.
Welcome to the lesson on lasers.

After completing this lesson, you should be able to:
- List laser risks.
- Identify strategies for laser safety.
## Overview & Risks

Lasers have many clinical uses.

Hazards of lasers include:
- **Laser plume**
- **Mechanical hazards**
- **Electrical hazards**
- **Chemical / gas hazards**
- **Fire hazards**
- **Eye or skin injury**

Click on each to learn more.

### Laser plume
Plume is the smoke formed when tissue is destroyed by a laser. Inhalation of plume can cause airway irritation and nausea. Plume can also contain infectious agents or cancerous cells.

### Mechanical hazards
Laser equipment can be large. This adds to operating room clutter. Clutter can be a hazard.

### Electrical hazards
Lasers have high-voltage power supplies. They also have cooling water supplies and liquid dyes. This creates an electrocution hazard.

### Chemical / gas hazards
Some lasers use liquid or gas in their operation. These liquids and gases can be carcinogenic. This can become a hazard if there is leakage.

### Fire hazards
Fires require oxygen, fuel, and ignition. All three are present in an operating room with a laser.

### Eye or skin injury
Both primary and reflected laser beams can burn the eyes or skin.
Medical staff who take part in laser procedures must be trained on the use and hazards of lasers.

Lasers should be:
- Chosen carefully
- Serviced regularly

Other factors that can help prevent laser accidents are:
- Proper design and layout of laser rooms
- Use of protective equipment

Let’s look at each of these.
In designing a laser room, take into account the following:

- **Nominal Hazard Zone (NHZ).** The NHZ is the area in which a person could suffer skin or eye damage if hit by a direct or reflected laser beam. Consider the NHZ when placing items in a laser room. Place items so that surgical team members will need to enter the NHZ as little as possible.

- **Windows and doors.** Glass windows may not protect people outside the room from misdirected or reflected laser beams. Similarly, doors with manual locks may not be the best protection against accidental entry into the laser room. Door locks that are automatically activated when the laser is activated are a better choice.
Also take into account:

- Walls and ceiling. Walls and ceilings should be non-reflective. Use matte paint or a non-reflective covering.
- Warning sign or light. Place a warning sign or light at all entry points to the room. This light should be activated automatically when the laser is activated.
- Layout. The direction of the laser beam should be away from all doors and windows.
Equipment considerations for laser safety include:

- **Laser safety eyewear.** Goggles provide only limited protection against the primary laser beam within the NHZ. However, they are fully protective against reflected beams.

- **Surgical equipment.** Standard surgical equipment is highly reflective. Reflected surgical beams are a major risk. They are often responsible for eye injury. Therefore, choose laser surgical equipment with low reflectivity. Reduce instrument reflectivity by black anodizing [glossary], sandblasting, or coating with a black polymer finish.

- **Reflective trolley / cart.** Carts are also highly reflective. Remove them from the laser room, if possible. If not, cover with drapes.
Equipment

Other equipment considerations are:

- Plume evacuator. A plume evacuator is particularly important if the surgical plume is likely to contain viruses or cancer cells.
- Laser-proof endotracheal (ET) tube. Standard ET tubes are very likely to ignite if hit by a laser beam. If an ET tube is needed, use a metal ET tube that is laser-proof.
- Fire extinguisher. Make sure a fire extinguisher is available.
- Gloves and masks. Always wear proper PPE when changing organic dyes in dye lasers.
A primary laser beam can cause injury. Reflected beams cannot.

| a. True |
| b. False |

### MULTIPLE CHOICE INTERACTION

Correct: B

A: Incorrect. This statement is false. Both primary and reflected beams can cause injury.

B: Correct. This statement is false. Both primary and reflected beams can cause injury.
Summary

You have completed the lesson on lasers.

Remember:
- Lasers are very useful clinically, but also pose risks.
- Take steps for laser safety.
Welcome to the lesson on single-use devices (SUDs)

After completing this lesson, you should be able to:

- List the steps in the pre-use inspection of an SUD.
- Identify potential risk of using reprocessed SUDs.
Objectives

SUDs are also known as disposable devices.

SUDs offer convenience.

However, there can be risks with:
- Initial use of disposable devices
- Use of reprocessed SUDs
Any device can have defects. Therefore, inspect all SUDs before use. See text box (at right) for more information.
Reprocessing SUDs is common in the healthcare industry. Reprocessing helps facilities:
- Cut costs.
- Reduce medical waste.

Commonly reprocessed SUDs include:
- Surgical saw blades
- Surgical drills
- Surgical staplers
- Laparoscopy scissors
- Orthodontic braces
- Electrophysiology catheters
- Electrosurgical electrodes and pencils
- ET tubes
- Balloon angioplasty catheters
- Biopsy forceps
- Umbilical scissors
- Gas masks
- Ophthalmic knives
- Irrigation syringes
- Surgical gowns
Risk of Reusing SUDs

Reprocessed SUDs have not been shown to increase risk of injury or other problems.

However, in theory, reprocessed SUDs could have increased risk.

For example, reusing SUDs might increase the risk of:
- Infection, because the SUD is no longer sterile from the package
- Device failure, because SUDs are not designed to withstand harsh re-sterilization procedures

Because of the potential risks, the FDA regulates hospitals and third-party vendors who reprocess SUDs.
Summary

You have completed the lesson on single-use devices.

Remember:
- Inspect all SUDs before use.
- Reprocessing and reuse of SUDs is common.
- In theory, SUDs may have an increased risk of infection and device failure.
- For this reason, the FDA regulates hospital and third-party vendors that reprocess SUDs.
<table>
<thead>
<tr>
<th>#</th>
<th>Term</th>
<th>Definition</th>
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<tbody>
<tr>
<td>1.</td>
<td>Safe Medical Devices Act of 1990</td>
<td>The Safe Medical Devices Act of 1990 (SMDA) set new reporting requirements for the medical device industry and users of medical devices. SMDA requires that facilities report any deaths and serious injuries that might have been caused by a device. SMDA also requires facilities to establish and maintain adverse event files.</td>
</tr>
<tr>
<td>2.</td>
<td>walk-away down control</td>
<td>bed height control that causes an electric bed to continue to lower even after the control switch is released</td>
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<tr>
<td>3.</td>
<td>momentary control</td>
<td>bed control that causes an electric bed to change position only as long as the control switch is held down</td>
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<td>4.</td>
<td>active electrode</td>
<td>ESU accessory that directs current flow to the operative site</td>
</tr>
<tr>
<td>5.</td>
<td>return electrode</td>
<td>ESU electrode that directs current flow from the patient back to the power unit; also known as a grounding pad, patient plate, dispersive electrode, or passive electrode</td>
</tr>
<tr>
<td>6.</td>
<td>electrosurgical unit</td>
<td>ESU; machine that produces energy for electrosurgery; also known as a Bovie, power unit, or generator</td>
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<td>7.</td>
<td>embolus (plural: emboli)</td>
<td>abnormal particle circulating in the blood</td>
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<td>8.</td>
<td>occlusion</td>
<td>blockage resulting in inability to infuse through a line</td>
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<td>9.</td>
<td>anodization</td>
<td>process in which the surface of a metal is converted to a coating with desirable properties</td>
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<tr>
<td>10.</td>
<td>JCAHO</td>
<td>Joint Commission for the Accreditation of Healthcare Organizations</td>
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<tr>
<td>11.</td>
<td>FDA</td>
<td>Food &amp; Drug Administration</td>
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<tr>
<td>12.</td>
<td>PPE</td>
<td>personal protective equipment; items of apparel that protect against exposure to hazards</td>
</tr>
<tr>
<td>13.</td>
<td>electrically isolated</td>
<td>referring to an electric circuit in which the current is not &quot;seeking ground&quot;</td>
</tr>
<tr>
<td>14.</td>
<td>ground-referenced</td>
<td>referring to an electric circuit in which current can leave the desired circuit by &quot;going to ground&quot;</td>
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<tr>
<td>15.</td>
<td>dexterity</td>
<td>skill and ease in use of the hands</td>
</tr>
<tr>
<td>16.</td>
<td>bolus</td>
<td>a single dose of drug or fluid given all at once</td>
</tr>
<tr>
<td>17.</td>
<td>pulmonary edema</td>
<td>accumulation of fluid in the lungs</td>
</tr>
<tr>
<td>18.</td>
<td>Luer lock</td>
<td>a threaded connection or port that reduces the likelihood of entry of air into syringes or IV devices</td>
</tr>
<tr>
<td>19.</td>
<td>disinfectant</td>
<td>an agent that will kill most of the microbes that it contacts</td>
</tr>
<tr>
<td>20.</td>
<td>sterilant</td>
<td>an agent that kills all of the microbes that it contacts</td>
</tr>
<tr>
<td>21.</td>
<td>carcinogen</td>
<td>cancer-causing agent</td>
</tr>
</tbody>
</table>
Pre-Assessment

1. Choose the true statement about medical device risks.
   a. An example of a clinical problem is poor device labeling.
   b. To reduce risk, devices should meet the needs of both users and patients.
   c. An example of a user problem is when a device has a software malfunction.
   d. An example of a device problem is an allergic reaction to materials in the device.
   
   Correct answer: B
   Rationale: Safe devices consider the needs of both the patient and the device user.

2. JCAHO requires accredited facilities to have equipment management programs.
   a. True
   b. False

   Correct answer: A
   Rationale: This statement is true.

3. The FDA criteria for a well designed device include:
   a. The device relies on the user’s strength and dexterity.
   b. The device is consistent with the experience of the user.
   c. The device requires the user to have specialized training.
   d. The device relies on the user’s mental math skills and memory.

   Correct Answer: B
   Rationale: A well-designed device is consistent with the experience of the user.

4. Choose the true statement about pediatric patients and electric bed safety.
   a. In pediatric wards, keep empty beds in their lowest position.
   b. Walk-away down controls are safer than momentary controls.
   c. A best practice is to unplug electric beds in pediatric care areas.
   d. Place children under the age of six in pedestal-style electric beds.

   Correct answer: A
   Rationale: Empty beds should be kept in their lowest position.

5. A serious risk of bed rails is entrapment and death by suffocation
   a. True
   b. False
Correct answer: A
Rationale: Bed rails can trap patients and lead to suffocation.

6. Choose the true statement about ethylene oxide (EtO).
   a. Heat-sensitive equipment may be sterilized using EtO.
   b. One of the advantages of EtO sterilization is that EtO is non-toxic.
   c. Steam sterilization can always be used in place of EtO sterilization.
   d. Glutaraldehyde is a non-toxic alternative to EtO for sterilizing equipment.

Correct answer: A
Rationale: Ethylene oxide is used commonly in healthcare facilities to sterilize heat-sensitive equipment.

7. One of the risks of infusion pump use is infiltration. Infiltration can lead to:
   a. Tissue death
   b. Air-in-line-alarm
   c. Venous air emboli
   d. Occlusion release bolus

Correct answer: A
Rationale: Infiltration happens when an infusion leaks into the tissues around the infusion site. This can lead to death of the tissues.

8. You are programming an infusion pump. To achieve the shortest possible time-to-alarm for an occlusion, you should:
   a. Set the flow rate as low as possible. Set the occlusion alarm pressure limit as low as possible.
   b. Set the flow rate as low as possible. Set the occlusion alarm pressure limit as high as possible.
   c. Set the flow rate as high as possible. Set the occlusion alarm pressure limit as low as possible.
   d. Set the flow rate as high as possible. Set the occlusion alarm pressure limit as high as possible.

Correct answer: C
Rationale: High flow rates and low occlusion alarm pressure limits shorten the time-to-alarm.

9. A patient is burned when electrosurgical current leaves the patient through an EKG lead. This type of burn is a(n):
   a. Dispersive burn
   b. Alternate site burn
   c. Active electrode burn
   d. Return electrode burn

Correct answer: B
Rationale: This describes an alternate site burn.
10. You are preparing a patient for electrosurgery. You should place the return electrode:
   a. On a hairy area, for insulation from the electric current
   b. On tissue directly over bone, to block deep current flow
   c. Over fatty tissue, for padding between deeper muscle and the electrode
   d. On a flat, muscular area, for proper electrical contact with the electrode

Correct answer: D
Rationale: Return electrodes should be placed over a flat, muscular area. Any hair should be shaved. Return electrodes should not be placed over fatty tissue or on tissue directly over bone. These areas do not provide the proper electrical conductivity.
Final Exam

Question Title: Question 1
Question: The FDA regulates hospital and third-party vendors that reprocess SUDs.

Answer 1: True
Answer 2: False

Correct Answer: True
Answer Rationale: This statement is true.

Question Title: Question 2
Question: Electric beds and pediatric patients are a risky mix. To reduce risk:

Answer 1: Unplug four-poster style electric beds in the pediatric unit.
Answer 2: Lock out patient controls for bed height on all electric beds.
Answer 3: Use only walk-away down controls on all pedestal-style beds.
Answer 4: Place children under the age of six in pedestal-style electric beds.

Correct Answer: Lock out patient controls for bed height on all electric beds.
Answer Rationale: Patient controls for bed height should be locked out on all electric beds.

Question Title: Question 3
Question: Choose the best practice for medical equipment safety:

Answer 1: Read and understand all instructions.
Answer 2: Reprocess all single-use devices for reuse.
Answer 3: Don't worry about signs of damage on a medical device.
Answer 4: Only do maintenance work when equipment malfunctions.

Correct Answer: Read and understand all directions.
Answer Rationale: Do not use a device if you do not understand the directions.

Question Title: Question 4
Question: ___________ is a possible clinical problem that could happen with use of a medical device.

Answer 1: Infection
Answer 2: Poor user training
Answer 3: Device malfunction
Answer 4: Defect in device design

Correct Answer: Infection
Answer Rationale: Infection is an example of a clinical problem. The other answer choices are user problems or device problems.

Question Title: Question 5
Question: Laser safety goggles fully protect against exposure to a primary laser beam.

Answer 1: True
Answer 2: False

Correct Answer: False
Answer Rationale: Goggles fully protect against reflected beams. They do not give full protection against the primary beam.

Question Title: Question 6
Question: An equipment management program for hospitals is:

Answer 1: An OSHA mandate
Answer 2: A JCAHO requirement
Answer 3: A method for reprocessing single-use devices
Answer 4: Necessary only for hospitals of more than 100 beds

Correct Answer: A JCAHO requirement
Answer Rationale: JCAHO requires accredited facilities to have an equipment management program.

Question Title: Question 7
Question: The Nominal Hazard Zone (NHZ) for a laser is the area:

Answer 1: Immediately outside a laser room
Answer 2: In the direct path of a primary laser beam
Answer 3: In which eyes or skin could be damaged by a laser beam
Answer 4: Including the laser room and all adjacent rooms and corridors
Correct Answer: In which eyes or skin could be damaged by a laser beam
Answer Rationale: The NHZ is the area in which a person could have skin or eye damage if hit by a laser beam.

Question Title: Question 8
Question: Which of the following is most likely to cause poor electrical contact between a patient and an ESU return electrode?

Answer 1: Placing the electrode over fatty tissue
Answer 2: Placing the electrode over muscular tissue
Answer 3: Using an electrode with fresh conductive gel
Answer 4: Shaving the skin prior to placing the electrode

Correct Answer: Placing the electrode over fatty tissue
Answer Rationale: Fatty tissue is poorly conductive. Therefore, this is not a good choice for return electrode placement.

Question Title: Question 9
Question: Non-glutaraldehyde disinfectants have certain disadvantages. These disinfectants:

Answer 1: Will harm device parts made of plastic
Answer 2: Are less effective than glutaraldehyde products
Answer 3: Take longer to work than glutaraldehyde products
Answer 4: Often contain agents that can damage the skin or eyes

Correct Answer: Often contain agents that can damage the skin or eyes
Answer Rationale: Non-glutaraldehyde disinfectants often contain chemicals that can damage the skin and eyes.

Question Title: Question 10
Question: Ethylene oxide-sterilized items should not be removed from the sterilizer with bare hands.

Answer 1: True
Answer 2: False

Correct Answer: True
Answer Rationale: Items should be removed using transfer carts, forceps, and gloves.