HealthStream Regulatory Script

Medical Equipment Safety
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Lesson 1: Introduction
Lesson 2: Equipment Safety Basics
Lesson 3: Hospital Beds
Lesson 4: Glutaraldehyde and Ethylene Oxide
Lesson 5: Infusion Pumps
Lesson 6: Electrosurgical Units
Lesson 7: Lasers
Lesson 8: Single-Use Devices
Welcome to the introductory lesson on medical equipment safety.

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 the Joint Commission.
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Course Rationale

The Institute of Medicine (IOM) estimates that medical devices cause serious injury to 1.3 million Americans each year.

With proper systems in place, many of these injuries can be prevented.

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

### Course Goals

After completing this course, you should be able to:

- Recognize factors that contribute to medical device risks
- Identify Joint Commission and FDA [glossary] contributions to medical device safety
- List the risks of selected medical devices
- Identify strategies for addressing each risk
This introductory lesson gave the course rationale and goals.

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.
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
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 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 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

Devices 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, the Joint Commission 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.
The Joint Commission 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: [glossary]

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

Safe equipment has built-in safeguards that prevent the most common and serious types of user problems!
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.
<table>
<thead>
<tr>
<th>Safe medical equipment meets the needs of:</th>
<th>MULTIPLE CHOICE INTERACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. Joint Commission and OSHA</td>
<td>Correct: B</td>
</tr>
<tr>
<td>b. The user and the patient</td>
<td>A, C, and D: Incorrect. The correct answer is B.</td>
</tr>
<tr>
<td>c. The manufacturer and the FDA</td>
<td>B: Correct.</td>
</tr>
<tr>
<td>d. The attending physician and the charge nurse</td>
<td></td>
</tr>
</tbody>
</table>
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.
- The Joint Commission 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.
Lesson 3: Hospital Bed Safety

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

FLASH ANIMATION: 3001.SWF/FLA
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 controls (not walk-away down) controls.
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

Unplugging an electric bed is not necessary if all precautions are followed.
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.
Electric Beds: Fire Risk

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 safety 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.
## Electric Beds: Fire Risk

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.
<table>
<thead>
<tr>
<th>Special Care Beds and Tables</th>
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</thead>
</table>

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 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.
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: Risk

Bed rails can be a cause of patient death.

In a Joint Commission 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 Joint Commission 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.
<table>
<thead>
<tr>
<th>Bed Rails: Reducing the Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>To help prevent adverse events with bed rails:</td>
</tr>
<tr>
<td>- Staff must be trained in the use of bed rails.</td>
</tr>
<tr>
<td>- Staff must be educated on the dangers of entrapment.</td>
</tr>
<tr>
<td>- Patients and their families also must be educated.</td>
</tr>
</tbody>
</table>

| NO IMAGE |
**Bed Rails: Reducing the Risk**

<table>
<thead>
<tr>
<th>Other practices that can address the risk of bed rails are:</th>
<th>For more information on testing beds for entrapment risk:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Test beds for gaps that pose a risk of entrapment. No gap should be large enough to pose a safety risk.</td>
<td></td>
</tr>
<tr>
<td>- Use bed rail netting or clear padding to fill gaps and openings. This fills gaps without blocking the view of the patient.</td>
<td></td>
</tr>
<tr>
<td>- 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.</td>
<td></td>
</tr>
<tr>
<td>- Lower beds and remove side rails.</td>
<td></td>
</tr>
</tbody>
</table>
Drag and drop listed items to their proper place in the chart.

**Bed / Bed Accessory**

- Electric Bed
- Special Care Bed
- Bed Rails

**Risk**

- Fatal crushing of pediatric patients
- Any unintended movement of patient across or off the bed
- Patient entrapment and death by suffocation
# 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.
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
### Overview & Risks

<table>
<thead>
<tr>
<th></th>
<th>NO IMAGE</th>
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</thead>
<tbody>
<tr>
<td>Glutaraldehyde is used as a high-level disinfectant [glossary] and sterilant [glossary].</td>
<td></td>
</tr>
<tr>
<td>Ethylene oxide is also used to sterilize heat-sensitive instruments.</td>
<td></td>
</tr>
<tr>
<td>Disinfection and sterilization of equipment are critical in healthcare.</td>
<td></td>
</tr>
<tr>
<td>However, glutaraldehyde and EtO are toxins that can put healthcare workers at risk.</td>
<td></td>
</tr>
</tbody>
</table>
Glutaraldehyde: Risks

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
- Drowsines
- 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)
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.
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

Exposures commonly occur when working with sterilizers or handing materials removed from the sterilizer.
To minimize worker exposure to EtO, other sterilization processes should be used whenever possible.

Other options include:
- Steam sterilization
- Ultraviolet irradiation
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.

For details, refer to *Title 29 of the Code of Federal Regulations (CFR) Part 1910.1047*
<table>
<thead>
<tr>
<th>True or False: The best way to prevent EtO exposure is to use another method for sterilizing instruments.</th>
</tr>
</thead>
<tbody>
<tr>
<td>a. True</td>
</tr>
<tr>
<td>b. False</td>
</tr>
</tbody>
</table>

**TRUE / FALSE INTERACTION**

Correct: A
A: Correct. This statement is true.
B: Incorrect. This statement is true.
## Summary

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

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

![Image: 5003.jpg]
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

**Oclusion 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.

Always take appropriate steps to clear occlusions safely!
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.
<table>
<thead>
<tr>
<th>Free Flow: Reducing the Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>To prevent free-flow, use only pumps with set-based free-flow protection.</td>
</tr>
</tbody>
</table>

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### 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

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**Morbidity and mortality of venous air emboli depend upon:**

- Volume of air introduced to the bloodstream
- Rate at which air enters the bloodstream
- Cardiorespiratory status of patient
- Patient position
Risks: Air-in-Line Alarm

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.

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**False Alarms**

False air-in-line alarms can occur if:
- The tubing is not pushed firmly into the air detector slot.
- There are any small particles on the tubing or the detector.
- The solution being infused is prone to frothing.
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:
   a. Clamp catheter when not in use.
   b. Purge all of the air from the tubing.
   c. Use only pumps with set-based free-flow protection.
   d. 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.
Summary

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.
Return Electrode Burns

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.
## Alternate Site Burns

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.

![Image: 6006.jpg](image)

**Proper electrical flow**
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.
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.
To help prevent alternate site burns:

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

a. An electrically isolated generator is used.
b. The return electrode is placed over muscular tissue.
c. Current leaves the patient through a pathway other than the return electrode.
d. 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.
## Introduction

Welcome to the lesson on lasers.

After completing this lesson, you should be able to:

- List laser risks
- Identify strategies for laser safety
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.
Laser Safety

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.
Room Design and Layout

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.
Room Design and Layout

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.
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.

<table>
<thead>
<tr>
<th>a. True</th>
<th>b. False</th>
</tr>
</thead>
</table>

**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.
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.

### Always perform an inspection prior to using a disposable device:

- Check package integrity.
- Verify package label.
- Check for any debris or unidentified material in the package.
- Check label instructions for proper usage (instructions can change).
- Verify that the device is complete and properly assembled.
- Verify that all lumens are patent and all balloons intact.
- Check for any external defects.
- Verify that connections and junctions are intact and secure.
- Verify that valves and ports are properly oriented and functional.
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.

Do reprocessed SUDs return to the clinician's hands with a higher risk of problems???
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.
# Course Glossary

<table>
<thead>
<tr>
<th>#</th>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<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>
</tr>
<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>
</tr>
<tr>
<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>
</tr>
<tr>
<td>7.</td>
<td>embolus (plural: emboli)</td>
<td>abnormal particle circulating in the blood</td>
</tr>
<tr>
<td>8.</td>
<td>occlusion</td>
<td>blockage resulting in inability to infuse through a line</td>
</tr>
<tr>
<td>9.</td>
<td>anodization</td>
<td>process in which the surface of a metal is converted to a coating with desirable properties</td>
</tr>
<tr>
<td>10.</td>
<td>FDA</td>
<td>Food &amp; Drug Administration</td>
</tr>
<tr>
<td>11.</td>
<td>PPE</td>
<td>personal protective equipment; items of apparel that protect against exposure to hazards</td>
</tr>
<tr>
<td>12.</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>13.</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>
</tr>
<tr>
<td>14.</td>
<td>dexterity</td>
<td>skill and ease in use of the hands</td>
</tr>
<tr>
<td>15.</td>
<td>bolus</td>
<td>a single dose of drug or fluid given all at once</td>
</tr>
<tr>
<td>16.</td>
<td>pulmonary edema</td>
<td>accumulation of fluid in the lungs</td>
</tr>
<tr>
<td>17.</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>18.</td>
<td>disinfectant</td>
<td>an agent that will kill most of the microbes that it contacts</td>
</tr>
<tr>
<td>19.</td>
<td>sterilant</td>
<td>an agent that kills all of the microbes that it contacts</td>
</tr>
<tr>
<td>20.</td>
<td>carcinogen</td>
<td>cancer-causing agent</td>
</tr>
</tbody>
</table>
Pre-Assessment

1. Which of the following is a factor that contributes to medical device risks?
   a. Patient sensitivity
   b. Clear device labeling
   c. Thorough user training
   d. Proper device maintenance

   Correct: A
   Rationale: Clinical problems, such as patient sensitivity, contribute to medical device risks.

2. Which of the following is a factor that contributes to medical device risks?
   a. Excellent device design
   b. Mechanical malfunctions
   c. Proper software functioning
   d. User-friendly device packaging

   Correct: B
   Rationale: Device problems, such as mechanical malfunctions, contribute to medical device risks.

3. What does the Joint Commission require of healthcare facilities to help minimize medical device risks?
   a. Life safety code
   b. Emergency action plan
   c. Equal employment practices
   d. Equipment management program

   Correct: D
   Rationale: The Joint Commission requires facilities to have an equipment management program, to help address medical device risks.

4. Under FDA guidelines, what is one feature of a well-designed device?
   a. The device allows the user to make fatal errors.
   b. The device requires the user to do mental math.
   c. The device requires the user to rely on memory.
   d. The device alerts the user to device-related problems.

   Correct: D
   Rationale: A well-designed device alerts the user to problems.
5. Which practice can help prevent injury/death associated with electric beds on pediatric units?
   a. Keep empty beds in the highest position
   b. Place children under the age of six in electric beds
   c. Lock out the patient control for bed height on all beds
   d. Enable walk-away down on all pedestal-style electric beds

   Correct: C
   Rationale: The patient control for bed height should be locked out.

6. What is a risk of exposure to glutaraldehyde?
   a. Cancer
   b. Nausea
   c. Diabetes
   d. Hypertension

   Correct: B
   Rationale: Exposure to glutaraldehyde can cause nausea.

7. Which practice can help prevent infiltration risks associated with infusion pump use?
   a. Use a large catheter
   b. Infuse into a small vein
   c. Check the infusion site frequently
   d. Avoid taping the catheter at the IV site

   Correct: C
   Rationale: To help prevent infiltration-related injury with an infusion pump, check the infusion site frequently.

8. What is the risk to patients when electrosurgical units are used?
   a. Burns
   b. Diarrhea
   c. Suffocation
   d. Venous air emboli

   Correct: A
   Rationale: With improper use of electrosurgical units, patients may suffer active electrode burns, return electrode burns, or alternate site burns.
9. Which best practice for a laser room can help protect against laser hazards?
   a. Use reflective paint on walls and ceilings
   b. Equip the room with doors with manual locks
   c. Place all key equipment in the nominal hazard zone (NHZ)
   d. Place the laser so the beam points away from doors and windows

Correct: D
Rationale: The laser should be placed so the beam points away from doors and windows.

10. What is a risk with single-use devices?
   a. Patent lumens
   b. Intact balloons
   c. Properly oriented valves
   d. Device failure after re-sterilization

Correct: D
Rationale: Reprocessed SUDs may have increased risk of device failure, because they are not designed to withstand harsh re-sterilization procedures.
1. Which of the following is a factor that contributes to medical device risks?
   a. User limitations
   b. Clear device instructions
   c. Proper electrical functioning
   d. Excellent manufacturing quality

Correct: A
Rationale: User problems, such as user limitations, contribute to medical device risks.

2. Which of the following is a factor that contributes to medical device risks?
   a. Obvious device use
   b. User-friendly device design
   c. Pre-existing patient conditions
   d. Proper mechanical functioning

Correct: C
Rationale: Clinical problems, such as a patient's pre-existing medical conditions, contribute to medical device risks.

3. Under Joint Commission standards, healthcare facilities must have an equipment management program. What is one component of this program?
   a. Equipment storage
   b. Equipment removal
   c. Equipment selection
   d. Equipment replacement

Correct: One component of an equipment management program is equipment selection.

4. Under FDA guidelines, what is one feature of a well-designed device?
   a. The device requires the user to be very strong.
   b. The device has labeling that is difficult to read.
   c. The device prevents the user from making fatal errors.
   d. The device is inconsistent with the experience of the user.

Correct: C
Rationale: A well-designed device will prevent the user from making fatal errors.
5. Which practice can help prevent fires started by electric beds?
   a. Cover the power cord with a rug
   b. Plug the power cord into a power strip
   c. Check the floor under and near the bed for dust and lint
   d. Use an extension cord between the bed's plug and the wall outlet

Correct: C  
Rationale: To help prevent fires involving electric beds, check on and around the bed for dust and lint.

6. Which practice can help limit healthcare worker exposure to glutaraldehyde?
   a. Dry-sweep pure glutaraldehyde
   b. Eat in areas where glutaraldehyde is used
   c. Use the minimum amount of glutaraldehyde needed
   d. Place trays of glutaraldehyde for soaking in open areas

Correct: C  
Rationale: Always use the minimum amount of glutaraldehyde needed to disinfect tools or devices.

7. What is a risk of infusion pumps?
   a. Infiltration
   b. Controlled flow
   c. Rapid time-to-alarm
   d. Accurate air-in-line detection

Correct: A  
Rationale: Infiltration is a risk with the use of infusion pumps.

8. Which practice can help prevent air emboli when using an infusion pump?
   a. Change containers only after they run dry
   b. Release catheter clamps during tubing changes
   c. Purge all air from tubing and syringes before use
   d. Release catheter clamps during injection cap changes

Correct: C  
Rationale: To help prevent air emboli, purge all air from tubing and syringes before use.
9. What is a hazard of lasers?
   a. Laser stun
   b. Laser chill
   c. Laser plume
   d. Laser bloom

Correct: C
Rationale: Laser plume, the smoke formed when a laser destroys tissue, is an irritant and can contain infectious agents or cancer cells.

10. What system has been put in place to manage the risks of reprocessed single-use devices (SUDs)?
   a. The FDA has banned the re-use of SUDs.
   b. The FDA regulates hospitals and vendors that reprocess SUDs.
   c. The Joint Commission fines healthcare facilities that re-use SUDs.
   d. The Joint Commission revokes accreditation status if a facility re-uses SUDs.

Correct: B
Rationale: Because of the potential risks of reusing SUDs, the FDA regulates hospitals and third-party vendors that reprocess SUDs.