2019 Device Safety Calendar

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DEVICE

APHERESIS / DIALYSIS MACHINE

Use error: Did not check blood line for air bubbles.

Potential for harm: **High**

CASE STUDY

- A patient was receiving plasma exchange therapy using an apheresis machine.
- The venous blood line was dislodged from the safety clamp.
- The patient died of an air embolus.

SAFETY TIP

Equip a **bubble trap** and **ultrasonic bubble detector** to the tubing safety clamp to ensure air does not enter the patient.

Source: https://www.sfda.gov.sa/en/medicaldevices/gcc/Workshops/Documents/CaseStudies_MedicalDeviceAccidents_SFDA.pdf

JAN2019

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DEVICE

DEFIBRILLATOR

Use error: Did not use compatible electrodes.
Potential for harm: **High**

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These devices are NOT meant to be used together.

CASE STUDY

- A patient was experiencing cardiac arrest.
- Staff attempted to defibrillate patient using paddles and nonconductive electrodes.
- No shock was delivered because the electricity was absorbed and not transmitted.
- The patient died.

SAFETY TIP

Differentiate electrodes with *nonconductive* foam backings intended for use *without* paddles from electrodes with *conductive* backings intended to be used *with* paddles.
Store these incompatible electrodes **separately**.

Source: https://www.sfda.gov.sa/en/medicaldevices/gcc/Workshops/Documents/CaseStudies_MedicalDeviceAccidents_SFDA.pdf

FEB2019

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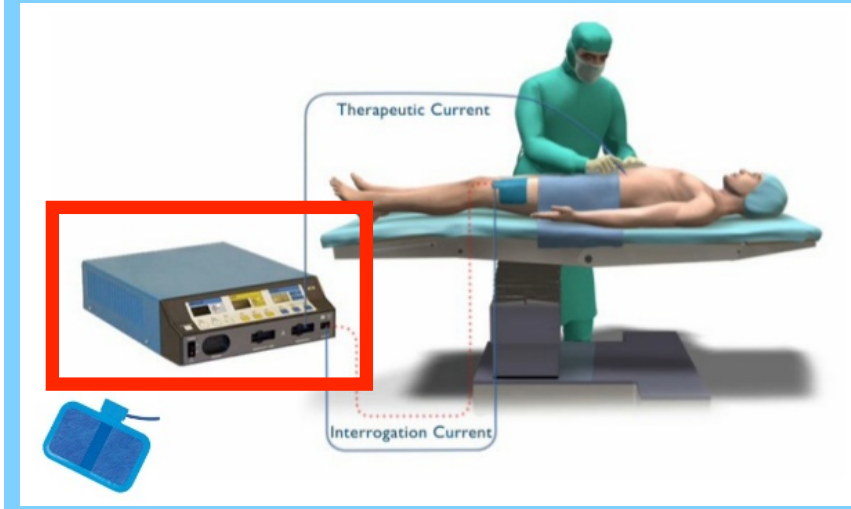
DEVICE

ELECTROSURGICAL GROUNDING PAD

Use error: Did not ensure good electrical contact between electrode and patient.
Potential for harm: **High**



Electrical contact may be disrupted by poor site preparation (e.g., not shaving hair from site), lack of conductive gel, defective materials, etc.

CASE STUDY

- A patient undergoing gynecologic surgery was prepped with an electrosurgical dispersive electrode.
- The surgeon attempted to activate the electrosurgical unit during surgery, to no avail.
- The patient received an electrical burn due to poor electrical contact with the dispersive electrode.

SAFETY TIP

Use a **return-electrode contact quality monitor** to ensure electrodes are in contact with patient.

Source: https://www.sfda.gov.sa/en/medicaldevices/gcc/Workshops/Documents/CaseStudies_MedicalDeviceAccidents_SFDA.pdf

MAR2019

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DEVICE

INFANT INCUBATOR

Use errors: Did not monitor the incubator and did not hear the alarms.
Potential for harm: **High**

A nurse did not hear any alarms but was drawn to the incubator when she noticed abnormal readings on the display.

CASE STUDY

- An infant was placed in an infant incubator.
- Loose wires in a power plug briefly interrupted power to the microprocessor controller of the incubator, and the temperature in the incubator rose, unchecked, to 180°F.
- The audible alarm was not heard.
- The infant died of hyperthermia.

SAFETY TIP

Implement temperature **limits** on incubators to prevent dangerous temperature levels.
Provide **multiple alarms of different modalities** (e.g., auditory *and* visual) to draw attention to problem.

Source: https://www.sfda.gov.sa/en/medicaldevices/gcc/Workshops/Documents/CaseStudies_MedicalDeviceAccidents_SFDA.pdf

APR2019

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DEVICE

MEDICAL GAS CYLINDER

Use error: Did not use the proper gas cylinder.
Potential for harm: **High**

CASE STUDY

- A surgeon required a cylinder of carbon dioxide for a laparoscopic surgery.
- A technician retrieved a cylinder with a partial label that read “Carbon Dioxide.”
- A flame appeared on the electrosurgical probe.
- The patient received a thermal burn on the internal abdominal wall but recovered.

SAFETY TIP

Differentiate different gas cylinders using not only labels but also clear **symbols** and **colors**.
Store cylinders **separately** to prevent mix-ups.

Source: https://www.sfda.gov.sa/en/medicaldevices/gcc/Workshops/Documents/CaseStudies_MedicalDeviceAccidents_SFDA.pdf

MAY2019

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DEVICE

LINEAR ACCELERATOR (LINAC)

Use error: Did not enter the prescribed dosage into the program.
Potential for harm: **High**

The user relied on the LINAC software to catch the erroneous dosage, but the dosage was viable for a different type of patient.

CASE STUDY

- A radiation technician used a linear accelerator (LINAC) to enter dosage data for a patient's radiation therapy.
- The patient received the wrong dose of radiation on repeated treatments.
- The patient was seriously injured by overdose.

SAFETY TIP

Provide **confirmation checks** in data-entry software to ensure the programmed dosage is the same as the prescribed dosage.

Source: https://www.sfda.gov.sa/en/medicaldevices/gcc/Workshops/Documents/CaseStudies_MedicalDeviceAccidents_SFDA.pdf

JUN2019

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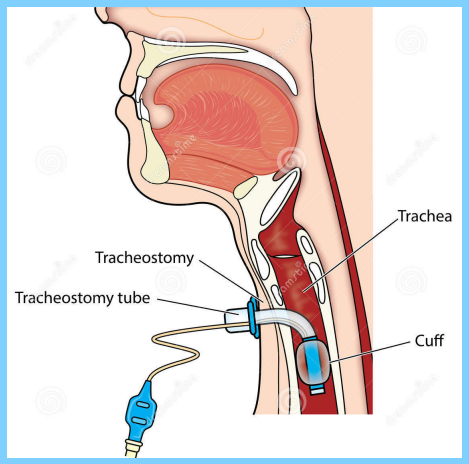
DEVICE

ELECTROSURGICAL UNIT

Use error: Did not follow the manufacturer's warnings.
Potential for harm: **High**

An electrosurgical unit should **not** be used to enter an airway during a tracheostomy, according to manufacturer's warnings.



CASE STUDY

- A patient with a tracheal tube was undergoing a tracheostomy.
- The surgeon used an electrosurgical unit to cut through the tracheal rings.
- The incision site erupted in flames, fueled by the 100% oxygen in the tracheal tube and the alcohol-based (flammable) prepping solution.
- The patient died from severe tracheal burn injuries.

SAFETY TIP

Provide a **warning** directly on the device reminding users not to use an electrosurgical unit to enter an airway during a tracheostomy, especially with 100% oxygen present.

Source: https://www.sfda.gov.sa/en/medicaldevices/gcc/Workshops/Documents/CaseStudies_MedicalDeviceAccidents_SFDA.pdf

JUL2019

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DEVICE

VENTILATOR

Use error: Did not quickly reconnect the dislodged tube from the ventilator.
Potential for harm: **High**

The screen of the ventilator could be used to indicate the source of the disconnection.

CASE STUDY

- A patient required an endotracheal tube to breathe.
- The patient was moved and the tube was accidentally dislodged from the ventilator.
- The clinician could not quickly locate the source of the disconnection.
- The patient died from hypoxia.

SAFETY TIP

Redesign ventilator **alarms** to indicate the location and type of disconnection so clinicians can quickly reconnect the tube and ventilator.

Source: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4849488/#B5

AUG2019

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DEVICE

Nd:YAG SURGICAL LASER

Use error: Did not use laser appropriately.
Potential for harm: **Medium**

The Nd:YAG laser is operated using a foot switch, which may be pressed accidentally.

CASE STUDY

- A surgeon used a neodymium:yttrium-aluminum-garnet (Nd:YAG) laser for an orthopedic procedure.
- Upon completion, the surgeon removed the probe and handed it to the scrub nurse.
- The surgeon accidentally pressed the laser foot switch and fired a burst of laser energy into the scrub nurse's face.
- The scrub nurse received a retinal burn.

SAFETY TIP

Add an **interlock**, such as a button on the probe to be pressed in addition to pressing the foot switch, to prevent inadvertent actuation of the laser.

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SEP2019

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DEVICE

INSULIN INFUSION PUMP

Use error: Did not check the pump to ensure proper insulin infusion.
Potential for harm: **High**

An insulin pump has a screen that can be used to display a warning message.

CASE STUDY

- A patient was prescribed an insulin infusion pump.
- Unbeknownst to the patient, the tube became blocked.
- Insulin was not delivered to the body.
- The patient died from hyperglycemia.

SAFETY TIP

Equip insulin pumps with **alarms** (e.g., sounds and vibrations) that signal dangerous glucose levels. Pumps should also require a **confirmation check** to ensure that the drug and infusion dose rate are correct.

Source: https://www.ncbi.nlm.nih.gov/books/NBK210047/

OCT2019

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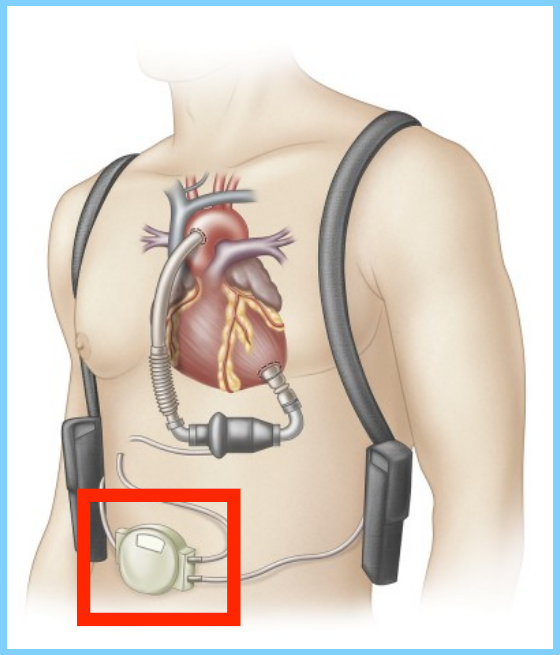
DEVICE

VENTRICULAR ASSIST DEVICE

Use error: Did not hear the alarm and did not resolve the problem.
Potential for harm: **High**



A ventricular assist device has a control unit that can be used to provide a warning message.

CASE STUDY

- A patient was using a ventricular assist device to provide circulatory support before cardiac surgery.
- While the patient was sleeping, the device emitted an auditory alarm.
- The patient did not hear the alarm.
- The patient died.

SAFETY TIP

Supplement auditory alarms with visual or tactile **alarms** to ensure attention is drawn to the problem.
Provide a clear and direct means of resolving the problem.

Source: https://www.ncbi.nlm.nih.gov/books/NBK210047/

NOV2019

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DEVICE

CENTRIFUGE

Use error: Did not wait for rotor to stop spinning before attempting to access samples.
Potential for harm: **High**

The lids of some centrifuges can be opened while the rotor is still spinning.

CASE STUDY

- A medical technologist loaded a centrifuge with blood samples for processing.
- After the spinning cycle completed, the technologist attempted to slow the centrifuge rotor using a pen cap.
- The pen cap smashed the sample tubes.
- The technologist was uninjured and uncontaminated.

SAFETY TIP

Design centrifuges with interlocked lids to **guard** users against accessing samples while the rotor is still moving to prevent harm.
Include an **emergency stop** button to terminate spinning cycle in case of emergency.

Source: https://www.sfda.gov.sa/en/medicaldevices/gcc/Workshops/Documents/CaseStudies_MedicalDeviceAccidents_SFDA.pdf

DEC2019

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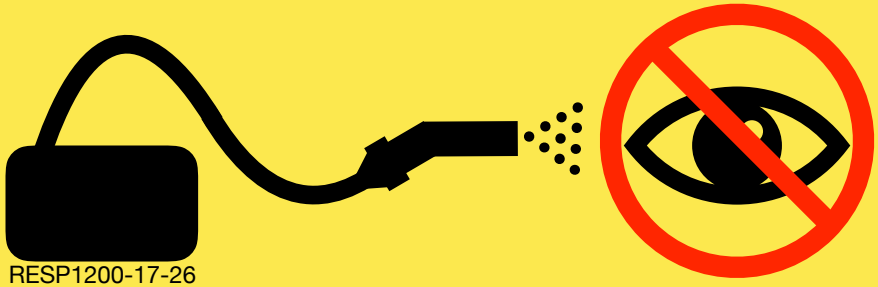
CAUTION



RESP1200-17-26

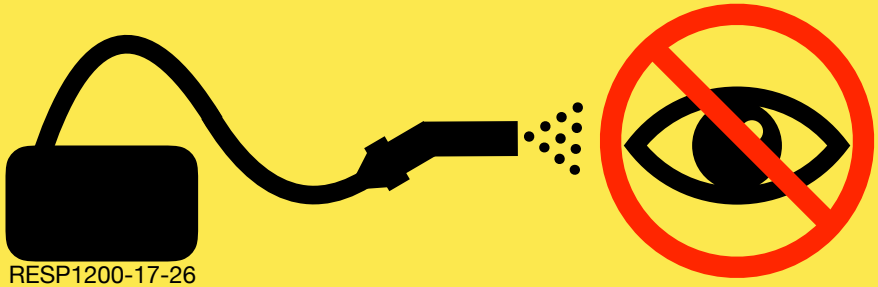
EYE IRRITANT

DO NOT DIRECT AT EYES

COULD CAUSE PERMANENT DAMAGE

FOR MORE INFORMATION, CALL: 1-800-345-6443

CAUTION



RESP1200-17-26

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