

# Intravascular Air-in-Line and Air Embolism Risks Associated with Infusion Pumps, Fluid Warmers, and Rapid Infusers: FDA Safety Communication

**Date Issued:** January 31, 2019

**Audience:**

- Health care professionals who use or who train users on infusion pumps, fluid warmers, and rapid infusers
- Health care professionals responsible for maintaining infusion pumps, fluid warmers, and rapid infusers
- Patients and caregivers who use or receive treatment with an infusion pump

**Specialties:**

Nurses, Nurse Practitioners, Physician Assistants, Pharmacists, Anesthesiologists, Certified Registered Nurse Anesthetist, Biomedical or Clinical Engineers, and Health Care Educators

**Purpose:**

The FDA is providing important safety information and recommendations to help users of infusion pumps, rapid infusers, fluid warmers, and their accessory devices reduce the risk of air being introduced in a blood vessel (air-in-line) and air embolism associated with these devices.

**Devices:**

- An **infusion pump** delivers fluids or medications, into a patient's body in controlled amounts. Infusion pumps are commonly used in hospitals and other health care settings by health care professionals but can also be used by patients and caregivers at home.
- A **fluid warmer** electrically warms fluids or blood products before they are given to a patient intravenously to help the patient maintain a normal body temperature. Fluid Warmers are generally used by trained health care professionals in a hospital or clinical setting for trauma or surgical patients.
- A **rapid infuser** is used to administer blood products and fluids at rapid rates to critically ill patients. They are generally used in a hospital or clinical setting by trained health care professionals.
- **Accessory devices** include intravenous (IV) tubing or administration sets. The tubing is inserted into the medication or fluid container, which runs through an infusion pump, fluid warmer, or rapid infuser, and into the patient's blood vessel through a catheter or port.

**Background:**

Air-in-line can be a potential risk to patients when fluids or medications are delivered into the body through a blood vessel. However, the clinical significance of air being infused into a blood vessel depends on several factors including:

- the amount of air,
- how quickly the air is delivered,
- specific patient factors (for example, patient age, patient size, the overall health of the patient).

If a significant amount of air is introduced into a blood vessel, it can travel through the blood vessels and become lodged in critical organs such as the brain, heart, or lungs. This is known as an “air embolism,” which can be life threatening because it may prevent oxygen from reaching those critical organs. Without oxygen, the tissues or organs become damaged.

As medical device technology continues to evolve, many devices used for infusions now have air-in-line sensors. When the device detects or senses air in the IV tubing, the device typically stops infusing, and generates an audible and/or visual alarm to alert the device user. These alarm sensors help prevent and reduce the risk of air embolism. As with any technology, sometimes these sensors or alarms can malfunction or fail for various reasons (for example, lack of proper device maintenance, damaged device, if air enters damaged IV tubing below where the device detects air in the line, if the air-in-line sensor has debris on it, etc.).

**Summary of Problem and Scope:**

While air-in-line sensors are meant to prevent, or reduce the risk of air embolisms, there can sometimes be false alarms or nuisance alarms. With a false alarm, the device may generate an air-in-line alarm when air is not present, or the amount of air detected is so small that it would not present a risk to the patient. When the device alarms, it stops the infusion, which may cause delays or an interruption of therapy. When a device stops infusing, this could be problematic if critical medications (for example, Epinephrine) are being infused. Some infusion devices offer different ranges or thresholds of air-in-line detection, which can be adjusted depending on the patient population. For example, an infusion pump air-in-line sensor setting used in a neonatal or pediatric patient population would likely be more sensitive than an adult patient population due to the patient size differences. In general, the setting of the air-in-line detector should be considered so that it is sensitive enough to help prevent a harmful amount of air reaching the patient, but not so sensitive that it generates false alarms too frequently.

From January 2016 through December 2018, approximately three percent of Medical Device Reports (MDRs) associated with infusion pumps, rapid infusers, fluid warmers, and accessory devices describe events with air-in-line issues. The majority of the air-in-line issues involve malfunctions of the air-in-line alarm or error messages displayed by the device which did not cause patient injury. A small number of reports describe:

- error messages which may have caused delays in therapy when critical medications were infused
- potential air embolisms and patient deaths, some of which were reported to be confirmed by imaging.

Air-in-line issues are not specific to any manufacturer or model of device. Due to the limited information provided in these reports and the likely presence of significant comorbidities, it is often unclear if a correlation exists between the infusion pump, rapid infuser, fluid warmer, or their accessories and patient outcome. Often, devices are not returned to the manufacturer for

further analysis, or accessory devices are discarded. MDRs are not, by themselves, definitive evidence of a faulty or defective medical device, and cannot be used to establish or compare rates of event occurrence.

### **Recommendations:**

FDA recommends that you Plan Ahead (for example, know how to use the device properly, and have a backup plan) and Monitor (for example, inspect and maintain the device, and watch for patient signs or symptoms). To help reduce the likelihood of serious adverse events associated with air-in-line, FDA recommends the following before, during, and after use of an infusion with a pump, rapid infuser, or fluid warmer:

#### **Health care Professionals**

- **Plan Ahead**

- Train and educate health care professionals on the risk of air embolisms, ways to reduce the risk, and how to appropriately use infusion devices. For example:
  - Know whether the devices you use have an air-in-line sensor.
  - Be aware that some devices have programmable settings for air-in-line sensors, and the threshold of the sensor can be changed depending on the patient population being treated (for example, neonates, adults).
  - These settings should be checked to ensure they are appropriate for the patient population using the devices.
  - Be aware of recommended troubleshooting techniques when an air-in-line alarm occurs to prevent a delay of therapy.
  - Follow your institutional policies or consult the applicable device's labeling (instructions for use) or the manufacturer for further information.
- When priming accessory devices (such as IV tubing), follow the applicable manufacturer's instructions for use to ensure the air is completely removed from the system.
- Inspect devices before use, and do not use damaged devices. For example:
  - IV tubing should be free from damage such as cuts, kinks, or disconnections before and during use, as these can be a source of air in the tubing.
  - If a device is dropped, or appears damaged (for example, cracked), do not use it and remove it from service. Follow your institutions policy or return it to the manufacturer for evaluation.
- If a patient is receiving a high-risk medication (for example, Epinephrine), be sure to have a backup plan in place. This may include having spare devices and accessories readily available.

- **Monitor**

- Recognize the signs and symptoms of an air embolism such as a sudden onset of chest pain or tightness, difficulty breathing or shortness of breath, lightheadedness, fainting, or confusion. In rare cases, this could include other neurologic symptoms. If a patient experiences a sudden onset of these symptoms, additional medical intervention (for example, rapid response team) may be needed.
- If the air-in-line sensor on your device is not working properly (for example, false alarms or failure to alarm), remove the device from service, and follow your institutions policy which may include returning it to a biomedical department, or sending it to the manufacturer for evaluation.

## Biomedical or Clinical Engineers

- Plan Ahead
  - Be aware that some devices have programmable settings for air-in-line sensors, and the threshold of the sensor can be changed depending on the patient population being treated (for example, neonates, adults). These settings should be checked to ensure they are appropriate for the patient population using the device.
  - Follow your institutional policies or consult the applicable device's labeling (instructions for use) or the manufacturer for further information.
- Monitor
  - Conduct appropriate device maintenance in accordance with the manufacturer's instructions to ensure proper functioning of the air-in-line sensors.
  - If a device is damaged and unable to be repaired by your facility, return it to the applicable manufacturer for evaluation and repair.

## Patients and Caregivers (for home use)

- Plan Ahead
  - Be sure you receive training and education on how to properly use an infusion pump. For example:
    - Know whether the devices you use have an air-in-line sensor.
    - Be aware of recommended troubleshooting techniques when an air-in-line alarm occurs.
    - If you have questions or problems, be sure to review the applicable device's labeling (instructions for use), or contact your health care professional.
  - When priming accessory devices (such as IV tubing), follow the applicable manufacturer's instructions for use to ensure the air is completely removed from the system.
  - Inspect devices before use, and do not use damaged devices. For example:
    - IV tubing should be free from damage such as cuts, kinks, or disconnections before and during use, as these can be a source of air in the tubing.
    - If an infusion pump is dropped, or appears damaged (for example, cracked), do not use it. Contact your health care professional or the manufacturer for further instructions.
  - If a delay or interruption of an infusion could cause significant harm to the patient, be sure to have a backup plan in place. This may include having a spare infusion pump and accessories readily available.
- Monitor
  - Be aware of the signs and symptoms of an air embolism such as a sudden onset of chest pain or tightness, difficulty breathing or shortness of breath, lightheadedness, fainting, or confusion. In rare cases, this could include other neurologic symptoms. If a patient experiences a sudden onset of these symptoms, additional medical intervention (for example, contact emergency personnel or call 911) may be needed.
  - If the air-in-line sensor on your infusion pump is not working properly (for example, false alarms or failure to alarm) despite troubleshooting, contact your health care professional.



For additional risk reduction recommendations, please refer to the FDA's [Infusion Pump Risk Reduction Strategies \(/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm202498.htm\)](/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm202498.htm).

#### Reporting Problems to the FDA:

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices. If you suspect an infusion pump, fluid warmer, rapid infusers or accessory devices are having problems such as, the pump showing signs of breakage or damage, including small chips or cracks, if an unexplained alarm occurs, or if the pump does not function as expected, we encourage you to file a voluntary report through [MedWatch \(/Safety/MedWatch/HowToReport/ucm2007306.htm\)](/Safety/MedWatch/HowToReport/ucm2007306.htm), the FDA Safety Information and Adverse Event Reporting program.

Device manufacturers and user facilities must comply with the applicable [Medical Device Reporting \(MDR\) regulations \(/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm\)](/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm).

Health care personnel employed by facilities that are subject to the [FDA's user facility reporting requirements \(/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm\)](/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/ReportingAdverseEvents/ucm2005737.htm) should follow the reporting procedures established by their facilities.

#### Other Resources:

FDA's [Infusion Pump Risk Reduction Strategies \(/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm202498.htm\)](/MedicalDevices/ProductsandMedicalProcedures/GeneralHospitalDevicesandSupplies/InfusionPumps/ucm202498.htm)

#### Contact Information:

If you have questions about this communication, please contact the Division of Industry and Consumer Education (DICE) at [DICE@FDA.HHS.GOV \(mailto:DICE@FDA.HHS.GOV\)](mailto:DICE@FDA.HHS.GOV), 800-638-2041 or 301-796-7100.

**More in Safety Communications**  
[\(/MedicalDevices/Safety/AlertsandNotices/default.htm\)](/MedicalDevices/Safety/AlertsandNotices/default.htm)

[2019 Safety Communications \(/MedicalDevices/Safety/AlertsandNotices/ucm630141.htm\)](/MedicalDevices/Safety/AlertsandNotices/ucm630141.htm)

[2018 Safety Communications \(/MedicalDevices/Safety/AlertsandNotices/ucm592582.htm\)](/MedicalDevices/Safety/AlertsandNotices/ucm592582.htm)

[2017 Safety Communications \(/MedicalDevices/Safety/AlertsandNotices/ucm553873.htm\)](/MedicalDevices/Safety/AlertsandNotices/ucm553873.htm)