المركز الوطني للبلاغات الأجهزة والمنتجات الطبية
NCMDR
National Center For Medical Devices Reporting

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Safety Communication

Intravascular Air-in-Line and Air Embolism Risks

Device/ Product Name:	Infusion Pumps, Fluid Warmers, and Rapid Infusers
Lot numbers/Serials:	Not specified
Manufacturer:	Not specified
Problem:	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. (You can read the complete Safety Alert that includes recommendations from Click Here.)
Recommendation/Actions:	Air-in-line issues are not specific to any manufacturer or model of device. Therefore, devices are not returned to the manufacturer for further analysis, or accessory devices are discarded. FDA recommends that you Plan Ahead to help reduce the likelihood of serious adverse events associated with air-in-line. • Train and educate health care professionals on the risk of air embolisms, ways to reduce the risk, and how to appropriately use infusion devices. • 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. • 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.

Healthcare Professionals should **report** any adverse events suspected to be associated with affected devices above (or other Medical Devices) to:

National Center for Medical Devices Reporting.
Medical Devices Sector
Saudi Food and Drug Authority
Postal Address: Saudi Arabia - Saudi Food and Drug Authority (3292)
North Ring Road - Al Nafal Unit (1)
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Sincerely,
NCMDR Team