

# Teleflex Medical Recalls Comfort Flo Humidification Systems Due to Malfunction That May Cause Water to Enter Airway

*The FDA has identified this as a Class I recall, the most serious type of recall. Use of these devices may cause serious injuries or death.*

## Recalled Product

- Name and Version: COMFORT FLO Humidification System, REF 2410, Humidifier Nebulizer Kit
- Product Code: GTIN 14026704659347
- Name and Version: COMFORT FLO Humidification System with Remote Temperature Port, REF 2414, Humidifier Nebulizer Kit
- Product Code: GTIN 14026704659354
- Name and Version: COMFORT FLO Corrugated Humidification System, REF 2415, Humidifier Nebulizer Kit
- Product Code: GTIN 14026704659361
- Name and Version: Corrugated COMFORT FLO Remote Temperature Port, REF 2416, Humidifier Nebulizer Kit
- Product Code: GTIN 14026704659378
- Model or Catalog Numbers: 2410; 2414; 2415; 2416.
- Manufacturing Dates: October 1, 2014 to June 30, 2019
- Distribution Dates: October 1, 2014 to October 31, 2019
- Devices Recalled in the U.S.: 398,320
- Date Initiated by Firm: December 13, 2019

## Device Use

The Comfort Flo Humidification System is used to provide a constant flow of heated and humidified breathing gases to patients. It can be used by neonatal, pediatric and adult patients in health care settings. The system is used with the Neptune Heated Humidifier with ConchaSmart Technology and ConchaTherm Neptune Heated Humidifier

## Reason for Recall

Teleflex Medical is recalling its Comfort Flo Humidification Systems due to the risk for water to flood the column and enter the circuit in the system. If water enters the circuit, water can enter

the nose and lungs of the patient.

The use of affected product may cause serious adverse health consequences, including low oxygen in the blood (desaturation) and the need for further treatment to prevent long term or serious injury.

There have been 102 complaints and 8 injuries with this device, including low oxygen in the blood (desaturation) and a slower than normal heart rate (bradycardia). There have been no reported deaths.

### **Who May be Affected**

- Health care providers using the Comfort Flo Humidification System
- All patient groups receiving treatment with the Comfort Flo Humidification System

### **What to Do**

On December 13, 2019, Teleflex Medical sent an Urgent Medical Device Recall Notice to customers informing them of the affected models and providing the following instructions:

- If you have affected stock:
  - Do not use and quarantine any products.
  - Identify all patients that are currently exposed to use of this product.
- Complete the Recall Acknowledge Form as soon as possible indicating whether you do or do not have stock. You may return the form by:
  - fax at 1-855-419-8507, Attn: Customer Service
  - email to [recalls@teleflex.com](mailto:recalls@teleflex.com) (<mailto:recalls@teleflex.com>)
  - give to your sales representative

A customer service representative will contact you with a Return Goods Authorization (RGA) number and provide instructions for the return of products.

### **Contact Information**

Customer who have questions or need additional information about this recall should contact Teleflex Customer Service at 1-866-396-2111, Monday through Friday between 8:00am and 7:00pm (Eastern Time).

### **Additional Resources:**

Medical Device Recall Database Entry

(<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?ID=178678>)

**How do I report a problem?**

Health care professionals and consumers may report adverse reactions or quality problems they experienced using these devices to MedWatch: The FDA Safety Information and Adverse Event Reporting Program (<https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home>) using an online form, regular mail, or FAX.