

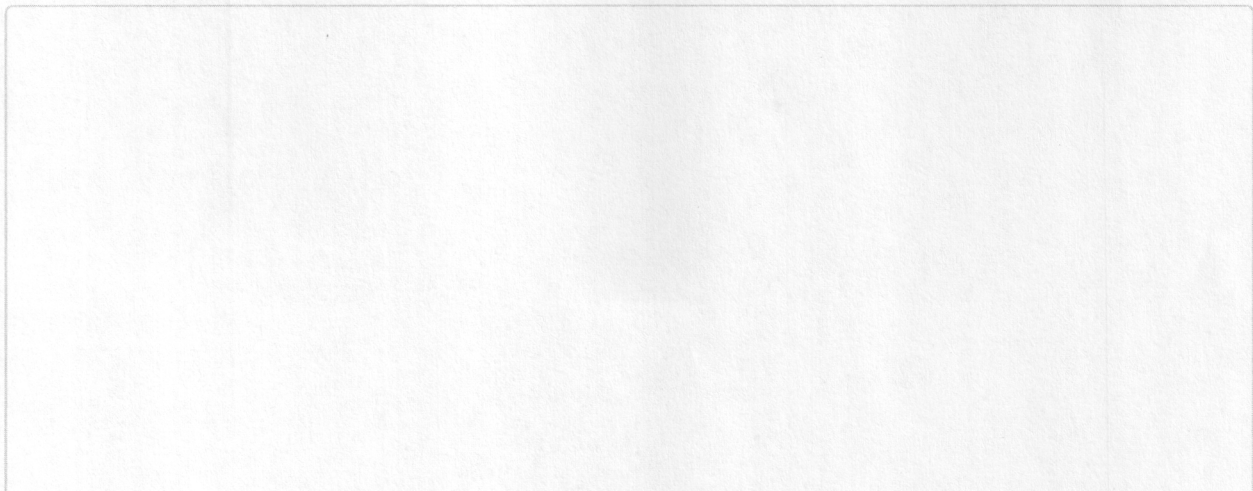
U.S. Food and Drug Administration
 Protecting and Promoting *Your* Health

CareFusion Recalls AVEA Ventilator Due to an Electrical Issue Which May Cause an Unexpected Shutdown

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:

Product Description	Product Numbers
AVEA Standard with Compressor ventilator-refurbished	R17312-xx (xx = 0-14)
AVEA Comprehensive ventilator	17310-xx (xx = 0 -14)
AVEA Standard ventilator	17311-xx (xx = 0 -14)
AVEA Standard with Compressor ventilator	17312-xx (x=0 -14)
AVEA Comprehensive ventilator-refurbished	R17310-xx (xx = 0-14)
AVEA Standard ventilator-refurbished	R17311-xx (xx = 0-14)
AVEA Standard with Compressor ventilator-refurbished	R17312-xx (xx= 0-14)
TCA Board	16542A
GDE- 1st Generation	16222-001-99
GDE	16650A
GDE-refurbished	R16650A
AVEA GDE/UIM upgrade kit	12283-PMN



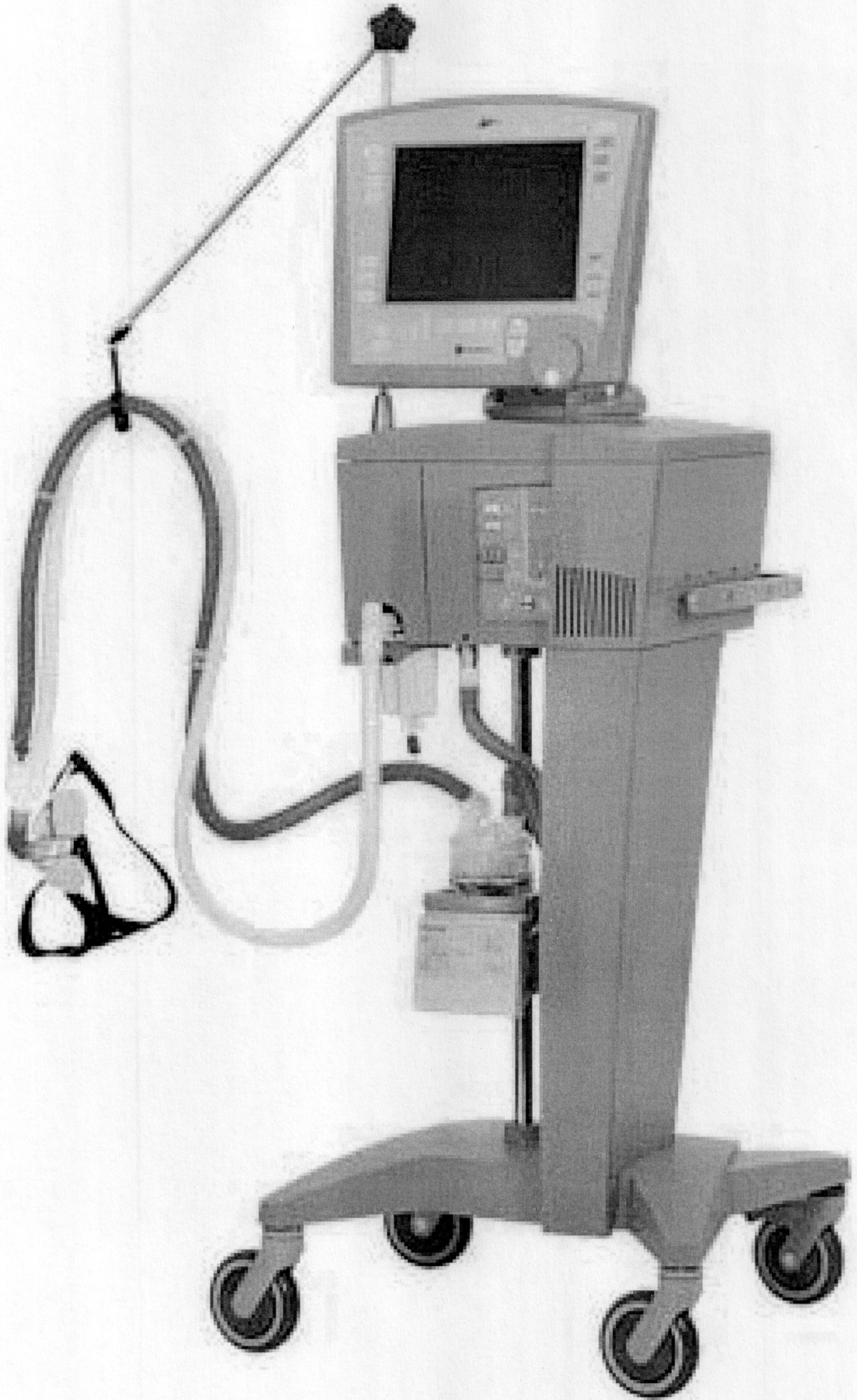


Image of recalled CareFusion AVEA ventilator

- Manufacturing Dates: November 13, 2016 to January 4, 2016
- Distribution Dates: to December 16, 2016 to February 15, 2016
- Devices Recalled in the U.S. 501 units distributed nationwide

Device Use

The AVEA ventilator is intended for continuous breathing support for infants, children and adults. The ventilator is only used in hospitals and other health care facilities.

Reason for Recall

CareFusion is recalling the AVEA Ventilator because of a faulty fuse on the ventilators' alarm board, which may cause the ventilator to unexpectedly shut down. If the ventilator shuts down, a patient may not receive necessary oxygen. The use of affected product may cause serious adverse health consequences, including death.

Who May be Affected

- Health care providers using AVEA ventilators
- All patient groups who may be using these ventilator systems for breathing support

What to Do

On May 17, 2016, CareFusion sent a "**Field Safety Notice**" (http://www.carefusion.com/Documents/alerts/RC_AVEA-Continuous-Use-Fuse-Recall-Letter-Intl-Customers_CL_EN.pdf) (<http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>) letter to affected health care facilities. The letter instructed health care professionals and consumers to:

- Complete and return the acknowledgement and receipt form
- After the response card is returned, CareFusion will schedule onsite remediation for affected devices
- Identify and remove affected ventilators as instructed in CareFusion's Field Safety Notice
- Report adverse events or quality problems experienced with use of the product to the FDA through:
 - **MedWatch Online (/Safety/MedWatch/HowToReport/default.htm)**
 - Phone: 800-FDA-1088

Contact Information

Health care professionals and consumers with questions are instructed to contact CareFusion at 888-526-6018 or **supportcenter@carefusion.com (mailto:supportcenter@carefusion.com)** with any questions related to this recall.

Date Recall Initiated:

May 17, 2016

Additional Resources:

CareFusion Press Release (<http://www.carefusion.com/customer-support/alerts-and-notices/medical-device-recall-for-avea-ventilator-continuous-use>)
(<http://www.fda.gov/AboutFDA/AboutThisWebsite/WebsitePolicies/Disclaimers/default.htm>)

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>)** either online, by regular mail or by FAX to 1-800-FDA-0178.

More in Medical Device Recalls
(</MedicalDevices/Safety/ListofRecalls/default.htm>)

2016 Medical Device Recalls (</MedicalDevices/Safety/ListofRecalls/ucm480134.htm>)

2015 Medical Device Recalls (</MedicalDevices/Safety/ListofRecalls/ucm429489.htm>)

2014 Medical Device Recalls (</MedicalDevices/Safety/ListofRecalls/ucm384921.htm>)