

SAN DIEGO, Sept. 30, 2013 /PRNewswire/ -- CareFusion issued the following update regarding its previously announced voluntary recall of AVEA ventilators.

®

The company initiated the voluntary recall on Sept. 3, 2013. **The FDA has classified this action as a Class I recall.**

A

Class I recall is defined as a reasonable probability of serious adverse health consequences or death associated with use of the defective units.

CareFusion announced a voluntary recall of AVEA® ventilators regarding barometric pressure sensor compensation when using the neonatal wye hot wire flow sensor. AVEA ventilators may experience an underreporting of tidal volume if used in conjunction with the neonatal hotwire flow sensor. The patient may receive a higher than expected tidal volume. The error is due to lack of barometric pressure sensor compensation.

While all AVEA ventilators fall under this voluntary recall, hospitals in locations at high elevations (higher than 5,000 feet above sea level) that are using the AVEA ventilator in the neonatal patient care setting are at greatest risk of this error. The level of underreporting between displayed flow and actual flow increases proportionately with altitude. CareFusion has received five complaints from a facility that was operating in the neonatal patient care settings and was located higher than 5,000 feet above sea level. No injuries have been directly attributed to this issue.

The Food and Drug Administration (FDA) has been notified of this recall.

Instructions to Customers

CareFusion does not require the return of the devices.

CareFusion advises its customers in locations higher than 5,000 feet above sea level using the AVEA ventilator in neonatal patient care settings with a wye hot wire flow sensor to take one of the following actions:

1. If using the AVEA Comprehensive ventilator, continue the use of the ventilator using the VarFlex™ single-patient use sensor (CareFusion part number 50000-40038), and discontinue use of the neonatal hotwire flow sensor until the software correction has been installed.
2. If using the AVEA Standard ventilator, discontinue use in neonatal patient care settings and contact CareFusion customer support.
3. If a hospital is located below 5,000 feet above sea level no action is necessary at this time.

Customer inquiries related to this action should be addressed to the CareFusion Customer Support Center at 1.800.562.6018 between the hours of 7:00 am to 4:30 pm PDT, Monday through Friday. Customers may also contact the company by email at SupportCenter@carefusion.com and the support center will follow up with customers.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA:

About CareFusion Corporation [CareFusion](#) (NYSE: [CFN](#)) is a global corporation serving the health care industry with products and services that help hospitals measurably improve the safety and quality of care. The company develops industry-leading technologies including

[Alaris](#)
®

infusion pumps,

[Pyxis](#)

CareFusion Provides Update On Voluntary Recall Of AVEA® Ventilator

Written by Australian Business

®

automated dispensing and
[patient identification systems](#)

,

[AVEA](#)

®

,

[AirLife](#)

®

and

[LTV](#)

®

[series](#)

ventilation and respiratory products,

[ChloraPrep](#)

®

products,

[MedMined](#)

®

services for data mining surveillance,

[V. Mueller](#)

®

surgical instruments, and an extensive line of

[products that support interventional medicine](#)

. CareFusion employs approximately 15,000 people across its global operations. More information may be found at

www.carefusion.com

.

SOURCE CareFusion Corp.

RELATED LINKS <http://www.carefusion.com>