CareFusion

URGENT Field Safety Corrective Action

Date: October, 2013

CareFusion 211, Inc.
22745 Savi Ranch Parkway
Yorba Linda, CA 92887, USA

Dear Business Partner:

Product Name: AVEA® ventilator all models

CareFusion has identified a potential risk associated with AVEA® ventilators when used at higher altitudes. A proactive complaint review identified an error in the barometric pressure compensation. CareFusion is voluntarily initiating a field correction of the affected devices to correct the error.
The published volume accuracy specification of the neonatal hotwire flow sensor is +/- 1ml + 10%.

Serial Number(s) of units in your area per our records are enclosed.

ISSUE:
AVEA ventilators may experience the underreporting of tidal volume if used in conjunction with the neonatal hotwire flow sensor, CareFusion part number 16465. This error is due to the barometric pressure sensor compensation. Clinically significant changes in barometric pressure are generally seen at altitudes greater than 5000 feet (1524 meters) above sea level (ASL).

While all AVEA ventilators fall under this voluntary Field Safety Corrective Action, hospitals in locations at high elevations (Higher than 5000 feet or 1524 meters above sea level) that are using the AVEA ventilator in the neonatal patient care setting are at greatest risk of this error.

Single patient use VarFlex™ sensors ***are not affected*** by this corrective action and will compensate for changes to atmospheric barometric pressure.

The adult and pediatric patient setting ***are not affected*** by this issue.

POTENTIAL RISK:
In cases where a patient is ventilated at an altitude of equal or greater than 1,524 meters ASL the ventilator may under report the delivery of tidal volume. The degree of which is based upon the altitude at the location of use.

For reference: The measurement error at 1,220 meters (approximately 681 mmHg) would be less than 10% and the error at 1,829 meters would be approximately 16-19%.

ACTIONS TO BE TAKEN BY CAREFUSION:
CareFusion has initiated a project to develop new version of software that will resolve this issue.

ACTION TO BE TAKEN BY BUSINESS PARTNER

- CareFusion does not require the return of your device(s).
- Once the software is available it must be installed on all AVEA units in your area.
- Please notify your competent authority or regulating agency and submit the FSCA report and the FSN (customer letter) to them, as per your local country regulations.
- Customers and distributor partners are asked to initiate one of the following actions:
    - If the location of your AVEA ventilator(s) is above 1,524 meters ASL and you are using the AVEA in the neonatal patient setting, customers are asked to take one of the following actions.
        - AVEA Comprehensive: Continue the use of your AVEA Comprehensive ventilator with the use of a VarFlex™ single patient use flow sensor, CareFusion part number 50000-40038 (10 pack).
        - AVEA Standard: Discontinue the use of your AVEA Standard ventilator in the neonatal patient setting.
    - If the location of your hospital is below 1,524 meters, or the ventilator is exclusively used in the adult and/or pediatric patient setting, no action is necessary other than to perform the necessary software update when made available.
- Return the enclosed response card within 5 days from date of receipt to expedite the correction process and acknowledge receipt of this notification.
- Translate enclosed letter if required per local regulatory requirements.
- Provide the customer letter and collect response cards.
- Return response cards immediately to CareFusion at the address provided.

CareFusion Contact	Contact Information	Areas of Support
CareFusion Technical Support	**+49 931 4972 393** **Support.CC.EU@carefusion.com**	Recall Related Questions

We appreciate your cooperation and we recognize the inconvenience this may cause your facility. Thank you for your support on this important matter.

Sincerely,

[redacted]

Enclosed:
List of affected units,
Customer Resonse Card
BP Response CardRES2013-AVEA-02