



Date: Jun 2015

Mexico

RE: FSCA-RES2015-AVEA-01

Dear customer,

A very small number of ventilators have developed false Ext High Ppeak and/or Circuit Occlusion alarms that the users were unable to clear. The AVEA® Ventilator is designed to alarm and stop ventilating if a Circuit Occlusion and/or Extended High Ppeak situation is detected. Alarms are annunciated visually and audibly. To this end, CareFusion initiated a voluntary recall to be certain that your AVEA® Ventilator will continue to operate as CareFusion designed it to do.

You may continue to use the AVEA® Ventilator since it is unlikely that your AVEA® Ventilator will experience an issue in normal use on patients. CareFusion aims to minimize inconvenience to you and your patients.

Please contact your local CareFusion Distributor for questions related to the Field Safety Corrective Action.

Yours Sincerely,



Donald J. Sherratt
Director of Regulatory Affairs and Compliance