

## Urgent Field Safety Notice

**FSN-2019-01**

Mar.4, 2019

Dear Valued Customer,

### **Re: Notice of stop use and return for inspection of O-Two eSeries Ventilators e700, e600 and e500**

On Feb.6, 2019 we issued a voluntary Field Safety Notice (FSN 2019-01) for our eSeries ventilators. Following a further risk analysis by our engineers we are now requesting that customers should **remove them from service and return immediately** for service inspection to O-Two Medical Technologies Inc. This applies to any units with serial numbers within the ranges listed below:

e700: EV70001 to EV70669;

e600: EV60001 to EV60126;

e500: EV50001 to EV50148.

In addition, during inspection, we will insert a secondary barrier layer between the mounting screws and main circuit board for added security.

It is still our firm belief that this to be a “one-off” incident occurring in a device that had been in use since 2015. However, our goal is, as always, to ensure the quality, efficacy and safety offered by our eSeries® devices.

Understanding your necessity for these devices to be available for your patients, we will undertake that the upgrade will be completed within 48 hours of receiving the returned devices so as to reduce the downtime of your ventilators. Please fill out the recall shipping form on the link in the email for the return process.

We apologize for any inconvenience and thank you for your cooperation during this process.

David Zhang



Quality Assurance Manager

