

Feb.7, 2019

URGENT: MEDICAL DEVICE CORRECTION

O-Two e700, e600 and e500

(1) Attention to Customer:

Life-Assist Inc
11277 Sunrise Park Dr., Rancho Cordova, CA 95742

Dear Valued Customer/Distributor,

(2) Purpose of this letter

The purpose of this letter is to advise you that O-Two Medical Technologies Inc. is voluntarily recalling **o_two e700, o_two e600 and o_two e500.**

(3) Reason for the Voluntary Recall:

On January 8th, 2019 we were made aware that an o_two e700 sales demonstration unit (SN EV70172-2015) caught fire during customer evaluation. There was no patient or staff injury. The device was disconnected and removed from the vehicle.

This device was manufactured in April 2015 and had been returned for service in October 2018 for the TFT screen to be replaced. The demonstration unit was received by O-Two on the 10th of January and inspected to ascertain the cause. It was found that during the replacement of the TFT screen, one of the screen retaining screws was incorrectly inserted. Due to this improper screw insertion the screw sat higher than normal allowing it to contact the underside of the main board causing the screw to rub against the bottom side of the board, wearing away the insulation layer and creating a short circuit.

(4) Risk to Health:

The fire may cause potential injury to the patient or user. However, we believe this to be a “one-off” incident occurring in a device that had been in use since 2015 and which had undergone screen replacement in 2018. To ensure this issue does not recur, O-Two Medical Technologies proposes a voluntary product correction to recall o_two e700, e600 and e500 automatic transport ventilators for inspection.

(5) Actions to be taken by the Customer/User:

- We are asking our customers to stop using and return immediately any of the following units that have undergone TFT screen replacement or have had service performed in the screen area;

EV70091-2014	EV70172-2015	EV70173-2015	EV70181-2015	EV70335-2016
EV70340-2016	EV70418-2017	EV70426-2017	EV70435-2017	EV70473-2017
EV70531-2017	EV60003-2014	EV60049-2016	EV50090-2016	

- For all other customers, we request that they return their units for service inspection in accordance with the arrangements made by your local supplier. Understanding your necessity for these devices to be available for your patients, we (or our authorized service centers) will undertake these actions as quickly as possible so as to reduce the downtime of your ventilators. In addition, during inspection, we will insert a secondary barrier layer between the mounting screws and main circuit board for added security;
- Please acknowledge receipt of this recall notification by completing and returning the attached “MEDICAL DEVICE RECALL RETURN RESPONSE” form, even if you have not any affected product on hand.

(6) Product and Distribution Information:

Please refer to the attached ‘Distribution summary List- USA’ for details.

(7) Type of Action by the Company:

We will inspect the returned units to ensure the TFT bracket assembly is correctly screwed down and insert a secondary barrier layer between the mounting screws and main circuit board for added security, and perform a 100% final inspection of the returned units

(8) OTHER INFORMATION:

Contact information:

- Name/Title: David Zhang/ QA Manager
- Address: 45A Armthorpe Road, Brampton, Ontario, Canada, L6T 5M4
- Telephone # (905) 792-6896, +1 (800) 387-3405 Email: david@otwo.com
- Days/Hours Available for calls: Monday through Friday, 7:30 AM to 3:30 PM Eastern Time.

Attachments of Acknowledgement and Product Replacement Forms (separate sheets)

We apologize for any inconvenience. Our goal is, as always, to ensure the quality, efficacy and safety offered by our eSeries® devices. We thank you for your cooperation during this process.

David Zhang



Quality Assurance Manager