

Recall Notification: O-Two Adult Ventilation Timer

Thursday, July 02, 2015

Dear Valued Life-Assist Customer,

According to our records you have purchased an item that has been recalled by the manufacturer. Please examine your stock to determine if you have the following product(s) with the affected lot number(s) in your possession.

Life-Assist Product Code	Model#	Product Description	Lot #(s)
OM1000TL	01BM1000	O-Two CPR Ventilation Timing Light, ADULT	079810
OTWO_01BM3201MOTLCS	01BM3201-MOTL-cs	BVM, SMART BAG ADULT W/ TIMING LIGHT, CS/12	140719, 140506

Reason for Recall: This recall has been initiated due to the malfunction of an O-Two Adult Ventilation Timer (01BM1000). The flash rate of the malfunctioning device was reported to be twice that of the rate noted on the label.

As the Adult Ventilation Timer is intended to guide the rescuer to provide ventilations at a rate appropriate for adult patients, there may be potential that an adult patient in cardiac arrest is ventilated at a faster rate than recommended, causing hyperventilation if the malfunctioning device is used.

Instructions for recall of the affected device:

- Methods of response to recall notification:
The recipient of this recall notification shall acknowledge its receipt through the following methods:
 - Fax: 1-905-677-2035; or
 - Email: david@otwo.com



- Instructions for return:
All consignees shall immediately carry out the following instructions:
 - Stop distribution or use of the above affected medical devices immediately;
 - Advise O-Two Medical Technologies the quantity of the affected medical devices in their possession;
 - Arrange with O-Two Medical Technologies for the return of the affected medical devices;
 - Extend the above instructions to additional consignees.
- Replacement:
O-Two Medical Technologies will inspect and ship the un-affected medical devices back within 10 working days after receipt of the return.

You may contact O-Two Medical Technologies directly at 800-387-3405 or Life-Assist, Inc. Customer Service at 800-824-6016 or customerservice@life-assist.com with any questions.

We apologize for any inconvenience.

