

Urgent Field Safety Notice

Name of the affected product: O-Two Adult Ventilation Timer (01BM1000)

FSCA-2015-01

Type of action: Return the affected medical devices to the manufacturer

Date: June 24, 2015

**Attention: AP Service
Nupark 49F, DK-7500 Holstebro, Denmark**

Details on affected devices:

Brand name: O-Two Adult Ventilation Timer

Model/Catalog number: 01BM1000

Target population: Adult patients

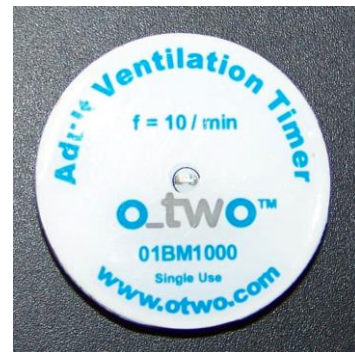
Quantity: 1 pc

Lot number: 079810 (reported in U.S.A.)

Shelf life: To end July 2016

Potentially affected devices in Europe:

- Denmark: 1 bag of 50 pcs, lot#078734, Order#123539;
- Finland: 1 bag of 50 pcs, lot#078734, Order#123624



Description of the problem:

There is one case reported in U.S. A. that the flash rate of the suspect Adult Ventilation Timer (01BM1000) is approximately twice that indicated on the device 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 malfunction device is used. Hyperventilation may reduce the efficacy of compressions during CPR.

Advise on action to be taken by the user:

O-Two Medical Technologies Inc. hereby proposes a Field Safety Corrective Action to recall the potentially affected O-Two Adult Ventilation Timer from Europe marketplace.

All consignees/users shall:

- 1) **Stop distribution or use of the following potentially affected medical devices;**
 - Denmark: lot#078734, 1 bag of 50 pcs, Order# 123539, Customer Order#ALLAN;
 - Finland: lot#078734, 1 bag of 50 pcs, Order# 123624, Customer Order#MINNA.

- 2) **Advise O-Two Medical Technologies the quantity of the affected medical devices in possession, as well as the details of any potentially affected devices distributed/transferred to other organisations;**

- 3) *Arrange with O-Two Medical Technologies for the return of the potentially affected medical devices;*
- 4) *Pass the Field Safety Notice to all those who need to be aware of it within the organisation and the organisation to which the device has been transferred*

Transmission of this Field Safety Notice: (if appropriate)

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (If appropriate)

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (If appropriate)

Please transfer this notice to other organisations on which this action has an impact. (If appropriate)

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. (if appropriate)

Contact reference person:

Name: David Zhang

Organisation: O-Two Medical Technologies Inc.

Address: 7575 Kimbel Street,
Mississauga, Ontario L5S 1C8
Canada

Contact details:

Fax: 1-905-677-2035; or

Email: david@otwo.com:

The undersign confirms that this notice has been notified the appropriate Regulatory Agency



David Zhang
QA Manager