

Urgent Field Safety Notice

Name of the affected product:

Equinox[®] Advantage N₂O/O₂ Analgesic Gas Mixing and Delivery System

FSCA-2017-01

Type of action: Return Equinox[®] Advantage to the manufacturer for correction

Date: December 22, 2017

Attention: *All consignees/distributors*

Details on affected devices:

Brand name: Equinox[®] Advantage

Model/Catalog number: 01EQ2000-XXX

Quantity: 1 pc (reported in Australia)

Serial number: EQ2016-2014

Manufacturing date: 2014-10-24

Potentially affected devices in Europe:



Country	QTY of sales	Serial Number
DENMARK	5	EQ2075-2015, EQ2104-2015, EQ2032-2016, EQ2074-2016, EQ2114-2016
SWEDEN	20	LIN0001-2017 to LIN0020-2017
GERMANY	2	EQ2145-2016, EQ2146-2016

Description of the problem:

The manufacturer O-Two Medical Technologies has been made aware of an incident with one of the Equinox[®] Advantage N₂O/O₂ mixers where the oxygen supply of the reported mixer (Model#: 01EQ2000, S/N#: EQ2016-2014) was cut off due to a disengaged piston seat in the equalizer that allowed 100% supply of nitrous oxide to be delivered to a patient.

The incident was reported to Australian TGA on Sep.27, 2017. A Recall for Product Correction in Australia was proposed by O-Two Medical and approved by TGA on Dec.18, 2017.

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 Equinox[®] Advantage N₂O/O₂ Analgesic Gas Mixing and Delivery Systems from Europe market.

All consignees/distributors shall:

- 1) *Stop distribution the potentially affected medical devices;*

- 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) *to allow you to continue to offer inhalation analgesia to your patients use an oxygen monitor with alarms on the output of the device (Refer to the enclosed Users' Manual (revision 10) for instructions) while we make arrangements for your units to be returned for upgrade*
- 5) *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)

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: 45A Armthorpe Road,
Brampton, Ontario, L6T 5M4
Canada

Contact details:

Fax: 1-905-799-1339; or

Email: david@otwo.com:

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



Signature
David Zhang
Quality Assurance Manager