Urgent Field Safety Notice

FSCA-2018-01

May 11, 2018

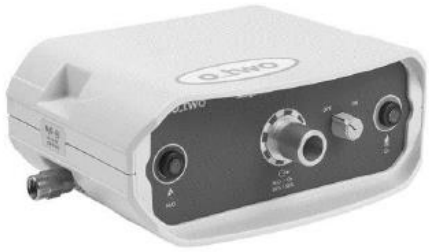
Name of the affected product:
Equinox® Relieve & Equinox® Advantage N_2O/O_2 Analgesic Gas Mixing and Delivery System.

Type of action: Return Equinox® Relieve and Equinox® Advantage to the manufacturer for product upgrade

Attention: *All consignees/distributors*

Details on affected devices:

Brand name: **Equinox® Relieve**
Model/Catalog number: 01EQ1000
Quantity: 15 pcs
Manufacturing date: Jul.2012 – Mar. 2018
Potentially affected devices in Europe:



Country	QTY of sales	Serial Number
GERMANY	15	EQ1056-13, EQ1615-17, EQ1616-17, EQ1617-17, EQ1618-17, EQ1882-17, EQ1883-17, EQ1884-17, EQ1885-17, EQ1886-17, EQ3007-18, EQ3008-18, EQ3009-18, EQ3010-18, EQ3011-18

Brand name: **Equinox® / Ventyo® Advantage**
Model/Catalog number: 01EQ2000-XXX
Quantity: 67 pcs
Manufacturing date: 2014-10-24 to 2018-03-31
Potentially affected devices in Europe:

Country	QTY of sales	Serial Number
DENMARK	5	EQ2075-2015, EQ2104-2015, EQ2032-2016, EQ2074-2016, EQ2114-2016
SWEDEN	60	LIN0001-2017 to LIN0040-2017, LIN0041-2018 to LIN0060-2018
GERMANY	2	EQ2145-2016, EQ2146-2016

O-Two Medical Technologies Inc.
45A Armthorpe Road, Brampton, Ontario, Canada, L6T 5M4
Office: +1 905 792-OTWO (6896) Toll Free: +1 800 387 3405 Fax: +1 905 799 1339
E-mail: resuscitation@otwo.com Website: www.otwo.com

Description of the problem:

On Apr.24, 2018 we received two (2) O_2/N_2O mixers (Serial numbers: CMI1194-2014 and CMI1196-2014) which were reported to have delivered higher levels of nitrous oxide than specification during routine testing. Our records show that neither of these units had been returned for service since they were manufactured in 2014. It was reported that there was no patient involvement in either case.

The O-Two Equinox® Relieve N_2O/O_2 Analgesic Gas Mixing and Delivery System is intended for delivering a self-administered, pre-set (50%/50%) mixture of nitrous oxide and oxygen, on demand, to a conscious, spontaneously breathing patient. Hence, the probability of this issue creating a health hazard is, based on our hazard evaluation, extremely low.

Advise on action to be taken by the user:

While the prolonged use of these units without any service mitigates in favor of the safety of the device, O-Two Medical Technologies Inc. hereby proposes the following Field Safety Corrective Action, asking our distributors/ customers to return Equinox® Relieve N_2O/O_2 Analgesic Gas Mixing and Delivery Systems from Europe market for product upgrade. The proposed upgrade is also extended to all Equinox® Advantage devices so as to standardize the upgrade across all Equinox mixer devices:

Further distribution of any remaining product should cease. Any stock shall be returned forthwith to O-Two Medical Technologies for product upgrade. To maintain the hospital's ability to provide inhalation analgesia during this product upgrade period, we recommend the device only be used with an oxygen monitor with alarms attached in accordance with our product manual (refer to the enclosed Users' Manual (01EQ2000, Rev.11) and (01EQ1000 Rev.7) for instructions).

Transmission of this Field Safety Notice:

This notice is to be distributed to all those within your organization that need to be made aware of its contents. It is also required to be distributed to all organisations/ customers where the potentially affected devices have been transferred/sold.

We apologize for any inconvenience this product upgrade may cause you. Our goal is to always ensure the quality, efficacy and safety offered by our Equinox® devices. Thank you for your cooperation during this process.

Please send fax to 1-905-799-1339 or email to david@otwo.com to acknowledge receipt of this Notification.

Contact reference person:

Name:	David Zhang
Organisation:	O-Two Medical Technologies Inc.
Address:	45A Armthorpe Road, Brampton, Ontario, L6T 5M4 Canada
Fax:	1-905-799-1339; or
Email:	david@otwo.com:

David Zhang
Quality Assurance Manager