partner for life

WEINMANN medical technology

WEINMANN Emergency Medical Technology GmbH + Co. KG ■ PO Box 57 01 53 ■ 22770 Hamburg, Germany

Company
Name
Address
Zip City
COUNTRY

Hamburg, April 2016

Important safety notice:
corrective measure to a medical device on the market

OXYWAY pressure reducer for Fast and Click types (including oxygen administrator): Deviation of the flow value

Dear Sir or Madam,

Quality and safety are our highest priority. That is why we wish to act as always in a consistent and transparent manner and **would ask you for your support in implementing a corrective measure**.

Addressee
Users and owners/operators of the above-mentioned products as well as specialist dealers

Medical devices affected
OXYWAY Fast I, II, and III with serial numbers 1506358 to 1602261
OXYWAY Click with serial numbers 1500596 to 1600243
Oxygen adminstrator with OXYWAY Click with serial numbers 1500004 to 1600009

OXYWAY Fix and OXYWAY Fine products are not affected.

Description of problem
The inhalation outlet of the above-mentioned pressure reducer is affected.
In some cases there has been a deviation between the set flow and the flow emanating from the inhalation connection.

The pressure output of the pressure reducers described is not affected – there is no restriction for use as a pressure supply for ventilators.
You can continue to use the pressure reducer in this manner without hesitation.

Cause
The cause is a technical change introduced in mid 2015 that can result in premature wear, and as a consequence, in a wrong dosing of the inhalation flow.
Frequent adjusting of the inhalation values fosters this behavior.

Corrective Action
Immediately after the problem was identified, production was changed back to the previous device status before the technical change.
A modification of all the above-listed products on the market must be performed by WEINMANN Emergency Technical Service. This will restore the device to the previous status.

This remedy is compulsory. The BfArM [Bundesinstitut für Arzneimittel und Medizinprodukte - Federal Institute for Drugs and Medical Devices] has been informed of the procedure.

WEINMANN Emergency
Medical Technology GmbH + Co. KG
Frohbösestraße 12 ■ 22525 Hamburg
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F: 040 88 18 96 480
E: info@weinmann-emt.de
www.weinmann-emergency.de
Zentrum für Produktion, Logistik, Service
Siebenstücken 14 ■ 24558 Henstedt-Ulzburg

Registergericht
Amtsgericht Hamburg
Abt. A, Nr. 115967
USt-IdNr. DE288367727
WEEE-Reg.-Nr. DE 47913245

Zertifiziertes QM-System
EG-Richtlinie 93/42/EWG, Anh. II
(EN ISO 9001/EN ISO 13485)

Komplementär
WEINMANN Emergency
Management GmbH, Hamburg
Registergericht
Amtsgericht Hamburg
Abt. B, Nr. 38144

Gläubiger-ID
DE35ZZZ00000353971

Geschäftsführung
Dipl.-Volksw. Marc Griefahn
Dipl.-Kfm. Philipp Schroeder
Dipl.-Volksw. André Schulte
Bankverbindungen
Deutsche Bank AG Hamburg
BLZ 200 700 00 ■ Konto 646963900
SWIFT DEUTDEHH
IBAN DE87200700000646963900

Hamburger Sparkasse AG
BLZ 200 505 50 ■ Konto 1032262667
SWIFT HASPDEHHXXX
IBAN DE44200505501032262667
Commerzbank AG Hamburg
BLZ 200 400 00 ■ Konto 632007100
SWIFT COBADEHHXXX
IBAN DE14200400000632007100

As an owner/operator, user, or specialist dealer, this is what you must do now:

- **All** affected pressure reducers (see above) **must be modified by WEINMANN Emergency in the Center for Production, Logistics, and Service**.
  a. Please contact WEINMANN Emergency to discuss further action with respect to your affected devices (please refer to “Contact” for contact details). Please use the attached reply form.
  b. Please refrain from the unsolicited submission of affected devices.

- Should you be in possession of any of the affected OXYWAYs, you may continue to use them until further action is clarified. **Before each operation, ensure that a flow is produced** by setting the pressure reducer to resting positions 5 and 12. Determine whether there is an audible flow difference between the positions.

  If you cannot determine any difference, you may not use this pressure reducer for inhalation.
  Note: This does not affect operation of the device at the pressure outlet.

- Please ensure that this **safety information** is brought to the attention of all users of the above-mentioned products and other people to be informed in your organization. If the products have been passed to third parties (e.g. applies to specialist dealers), **please provide them with a copy of this information (if applicable, also to your customers).**

- Please use the attached reply form **to confirm receipt of this letter and that it has been passed on**.

Contact
If you have any questions, please contact us directly – we will of course be happy to answer any questions you may have. If required, please feel free to contact your Area Manager or our Customer Service,
Tel: +49 40 88 18 96 - 120, e-mail: CustomerService@weinmann-emt.de

Yours sincerely,

WEINMANN Emergency
Medical Technology GmbH + Co. KG

André Schulte
Managing Director

ppa. Dennis Horstmann
Authorized Signatory
Head of Supply Chain and Quality Management

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SWIFT COBADEHHXXX
IBAN DE14200400000632007100

Report form

Corrective measure for OXYWAY pressure reducer (Fast and Click types (including oxygen administrator)), April 2016

Original letter sent to:
Company
Name
Address
Zip City
COUNTRY

Please complete this reply form in full and send it by fax, e-mail or post to:

Fax: **+49 40 88 18 96 - 481**
e-mail: **CustomerService@weinmann-emt.de**

WEINMANN Emergency Medical Technology GmbH + Co. KG
Customer Service
Frohbösestraße 12
22525 Hamburg, Germany
GERMANY

Please complete in full in block capitals:
☐ **Company details are identical to those of the addressee above.**
☐ **Company details differ from those of the addressee above as follows:**

Your customer no.: _____

Company + address: _____

_____

_____

☐ **I hereby confirm receipt of this letter** and that I **have read and understood its contents**.**This letter has been brought to the attention of all users of the product and other people in my organization who need to be informed**.
If the products have been passed on to third parties (applies to specialist dealers, for example), a **copy of this information has been passed on to them**.

I have the following OXYWAY device types:

Item number	Serial number

Item number	Serial number

_____ _____
Date, signature Name (in block letters)

_____ _____
Position (in block letters) E-mail (in block letters)