

URGENT FIELD SAFETY NOTICE **DISTRIBUTORS**

Commercial name:	Various Unomedical High Concentration Oxygen Masks (see Attachment 1 for full details)
Issue Date:	31 st August 2017
REF No:	See Attachment 1
LOT No:	See Attachment 1
FSCA ID:	2017-001B
Type of action:	Recall / Product Disposal

This Field Safety Notice (2017-001B) has been provided to add two additional LOTs to the original action documented in Field Safety Notice (2017-001) issued on xx/mm/yyyy. See Attachment 1 for full details.

Please note that this action only applies to specific product codes and associated LOT numbers and does not affect all product codes and LOTs of High Concentration Oxygen Masks.

Description of the problem:

ConvaTec/Unomedical has voluntarily initiated a global recall of specific product codes and associated LOTs/batches of High Concentration Oxygen Masks.

An internal assessment of product reports has confirmed that these devices are not meeting our expectations or those of our customers. In some cases, the tubing has been found to disconnect from the oxygen mask, prior to use or during use, causing a disruption in supply of oxygen.

High Concentration Oxygen Masks are intended to deliver high concentration oxygen to patient airways.

Only the identified product part codes and associated lot numbers within this notice have the known potential to malfunction and disrupt the supply of oxygen to patients.

For this reason and to address any potential risk of harm, all of the affected products should **not be used**. If you believe any affected products remain in your inventory, please contact your Regional contact.

Product Identification Procedure:

The only way to identify affected product is by comparing product code and lot number to the recalled product list (see Attachment 1). There is no other discernable difference between affected and unaffected product.

See Attachment 2 for example package labeling that highlights the location of the product code and lot number on the device label which is located on the primary packaging and/or the shipping carton. The product code (reference number) is preceded by the word 'REF'. The lot number is preceded by the word 'LOT'.

Advice on action to be taken by distributor.

Our records show that you have taken delivery of affected product. Please follow the steps below:

1. Please examine both the enclosed questionnaires. Immediately stop distributing and quarantine all affected lots.
2. Please forward copies of the 'Field Safety Notice END USERS' to your customers, asking them to return the affected products to you along with a completed 'Recall Response Form for END USERS'.
3. When the completed Response Form(s) have been returned to you, please complete the 'Recall Response Form for DISTRIBUTORS' and contact your ConvaTec/Unomedical 'Regional contact' (see page 3) for further instructions on how to dispose of affected product and to arrange credit. New orders will need to be raised. To place new purchase orders for replacement stock please reference Attachment 3 which details product codes available for order.
4. Please also return the completed 'Recall Response Form for DISTRIBUTORS', and all 'Recall Response Form for END USERS' to your 'Regional contact' via Fax/ E-mail.

PLEASE PROVIDE A COMPLETED RESPONSE AS SOON AS POSSIBLE.

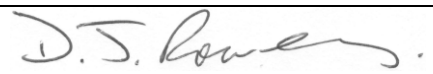
Continue to report any adverse events involving this product to the ConvaTec Customer Care Line (see Regional contact list for details).

Transmission of this Field Safety Notice:

This notice should be sent to all others who have received the affected High Concentration Oxygen Masks products within your organization or to any organization where the affected devices have been transferred. ConvaTec apologizes for any inconvenience this may cause. If you have any questions, please contact your distributor or local ConvaTec/Unomedical representative (see Regional contact list for details).

The relevant National Authorities have been advised about this Field Safety Corrective Action.

Authorisation:

<u>Name</u> Duncan Rowley	<u>Title</u> Director, Regulatory Affairs and Quality Assurance, EMEA	<u>Address</u> ConvaTec Limited, First Avenue, Deeside Industrial Park, Deeside, CH5 2NU, U.K.	
<u>Date</u> 31 st August 2017	<u>Signature</u> 		

'Regional contact' for this Field Safety Corrective Action:**France / Saudi Arabia / Switzerland**

Tel: + 41 (0) 52 630 54 01

Fax: +41 (0) 52 630 54 99

Email: ccc.customerservice@convatec.com**Denmark**

Tel: +45 4816 7030

Fax: +45 8025 3413

Email: customerservicenordic@convatec.com**Finland**

Tel: +358 (0) 20 7659 630

Email: mail.fi@convatec.com**Norway**

Tel: +47 22686095

Fax: + 47 80019602

Email: customerservicenordic@convatec.com**Sweden**

Tel: +46 (0)42 332010

Fax: +46 200887486

Email: customerservicenordic@convatec.com**United Kingdom**

Tel: +44 (0) 1244 832206

Fax: 0800 279 9004

Email: unomedical-uk.customerservice@convatec.com



RECALL RESPONSE FORM for DISTRIBUTORS
URGENT FIELD SAFETY NOTICE
PLEASE COMPLETE AND RETURN by Fax/Email

Consignee of the device:

Consignee Account No:	
Consignee Name:	
Consignee Address:	

The following High Concentration Oxygen Masks have been distributed to your facility:

Invoice #	Sales Order #	Product Code / REF No.	SAP Code	LOT No.	Quantity Delivered (pieces)

Please answer each of the following.

1. Have You Distributed the Product Further? NO YES*
 If YES, have you notified down to your customer? NO YES
 *If NO explain why not:

2. We have NO affected product.
 3. We have the following affected product:

Record quantity (pieces) for each LOT to be disposed:

LOT No.	Units on Hand	LOT No.	Units on Hand	LOT No.	Units on Hand	LOT No.	Units on Hand	LOT No.	Units on Hand

Provide details of affected High Concentration Oxygen Masks that were distributed to your customers:

Customer Name	Product Code / REF No.	SAP Code	LOT No.	Quantity (pieces)

FORM Completed and Returned From:

Name (CAPITAL LETTERS):	
Position:	
Company Name:	
Address:	
Phone No:	
Signature:	
Date (dd/mm/yyyy):	

- As requested, I have also provided a copy of all 'Recall Response Forms for END USERS' returned from customers who received affected product (please tick to confirm).

Attachment 1:
Product Codes & Lot Numbers affected

Product Code / REF No.	SAP Code	Description	LOT No's.
104MM	1302097	Rebreathing mask, Reservoir bag, with Tubing	105631
106MM	1702436	Oxygen Mask, Adult High Concentration Non-Rebreather 2.1 m (7') Oxygen Tubing	100733, 104106, 104798, 100721, 109824
108-E	1300168	Non-Rebreather Oxygen Mask, Adult High Concentration with 2.1 m (7') Oxygen Tubing	102766, 102785, 102726, 102352, 105451, 109186
108MM	1705302	Non-Rebreather Oxygen Mask, Adult High Concentration with 2.1 m (7') Oxygen Tubing	100281, 100709, 100729, 101923, 103180, 103265, 103691, 103714, 104104, 105987, 110558
3226-E	1308753	Non-Rebreather Oxygen Mask, Pediatric High Concentration with 2.1 m (7') Oxygen Tubing	102727
3226MM	1307553	Non-Rebreather Oxygen Mask, Pediatric High Concentration with 2.1 m (7') Oxygen Tubing	100720, 101141
3230MM	1302405	Non-Rebreather Oxygen Mask, Pediatric High Concentration with 2.1 m (7') Oxygen Tubing	104906, 105181
9108MM	1267152	Non-Rebreather Oxygen Mask, Adult High Concentration with 2.1 m (7') Oxygen Tubing	100232, 100694, 100918, 101639, 101897, 103067, 104846, 104848, 105453

Product Codes & Lot Numbers affected – Part B

Product Code / REF No.	SAP Code	Description	LOT No's.
106MM	1702436	Oxygen Mask, Adult High Concentration Non-Rebreather 2.1 m (7') Oxygen Tubing	13-32
108MM	1705302	Non-Rebreather Oxygen Mask, Adult High Concentration with 2.1 m (7') Oxygen Tubing	13-32, 105471

Attachment 2: Example Package Labeling

Product Code

REF 9108MM

GB **Non-Rebreather Mask, Adult with 2.1 m (7') Oxygen Tubing "No-Crush"**
 D **Verlängerte Nicht-Rückatmungs-Sauerstoffmaske mit Schlauch für die Erwachsene**
 DK **Forlængret åndemaske, ikke til genindånding, med slange for Voksne**
 F **Adulte Masque à oxygène, allongé, sans réinhalation avec tube**
 GR **Επιπλέον Εμπύση Μόνο Οξυγόνου Μυ-Επιστροφής Εκπνεύσεως Αδούλου με σωλήνα**
 I **Maschera a ossigeno Adult allungata e a circuito di non riorespirazione, con tubo**
 N **Avång oxygenmask utan återandning för Vuxna med slange**
 E **Mascarilla Adulto de No-Reinhalação con Tubo de Oxígeno de 2.1 m (7') "No-Colapsable"**
 NL **Langwerpig Zuurstofmasker zonder terugloopbeademing Volwassenen met slang**
 P **Máscara de oxigênio alongada de Não re-inalação Adulto com tubo**
 PL **Maska tlenowa Dla Dorosłych, z drzwem**
 R **Маска интентационическая с отверстием для выхода наружу регенерационная с соединительной трубкой**
 S **Åvång syrgasmask utan återandning för Vuxna med slang**
 SF **Aikahätken pitää takaisinhengitystä estäviä heppoisimmat, Adult**

Product Code

REF 9108MM

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 SF **Aikahätken pitää takaisinhengitystä estäviä heppoisimmat, Adult**

Unomedical Inc. 7701 S. Ware Rd. McAllen, Texas 78503 USA Phone # +1 956-853-8472 www.unomedical.com

ConvaTec Limited, First Avenue, Dennis, Florida, 32526 USA

Made in Mexico

Lot Number: LOT 112094

2020-06

Label # LDR9108MM / Rev. 01/14

Barcode: 10844249001629

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ConvaTec Limited, First Avenue, Dennis, Florida, 32526 USA

Made in Mexico

Lot Number: LOT 112094

2020-06

Label # LDR9108MM / Rev. 01/14

Barcode: 8 44249 00162 2

Product Code: REF 9108MM

Lot Number: LOT 112094

2020-06

GB **Non-Rebreather Mask, Adult with 2.1 m (7') Oxygen Tubing "No-Crush"**
 D **Verlängerte Nicht-Rückatmungs-Sauerstoffmaske mit Schlauch für die Erwachsene**
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Barcode: 20844249001626

5x10

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Attachment 3: Available Product Codes

ConvaTec has recently expanded and enhanced their range of Respiratory Care products. In addition to a wider choice of products, the new range offers various additional benefits, such as:

- Complete replacement of phthalates (incl. DEHP)
- Products standardized with universal (Fits-All™) connector for connection either to an oxygen fitting, or directly to the flow-meter screw - and all oxygen tubing standardized to crush-resistant lumen (No-Crush™ tubing)
- Packaging standardization to sealed sub-packs of 10 pieces for eased on-site distribution to functional areas.

In case of re-ordering of any of the affected old product codes, ConvaTec will provide the latest generation of products which will have new Product Codes. Please follow the correct reordering process and supply a purchase order number.

OLD Product Code / REF No.	NEW Product Code / REF No.	NEW Product Description
104MM	93-104MM	Oxygen Mask, High Concentration Rebreather, 2.1m oxygen No-Crush™ safety tubing and Fits-All™ connector, Adult, 10x50pcs
106MM	93-108MM	Oxygen Mask, High Concentration Non-Rebreather, 2.1m oxygen No-Crush™ safety tubing and Fits-All™ connector, Adult, 10x50pcs
108-E	93-108MM	Oxygen Mask, High Concentration Non-Rebreather, 2.1m oxygen No-Crush™ safety tubing and Fits-All™ connector, Adult, 10x50pcs
108MM	93-108MM	Oxygen Mask, High Concentration Non-Rebreather, 2.1m oxygen No-Crush™ safety tubing and Fits-All™ connector, Adult, 10x50pcs
3226-E	93-230MM	Oxygen Mask, High Concentration Non-Rebreather, 2.1m oxygen No-Crush™ safety tubing and Fits-All™ connector, Pediatric, 10x50pcs
3226MM	93-230MM	Oxygen Mask, High Concentration Non-Rebreather, 2.1m oxygen No-Crush™ safety tubing and Fits-All™ connector, Pediatric, 10x50pcs
3230MM	93-230MM	Oxygen Mask, High Concentration Non-Rebreather, 2.1m oxygen No-Crush™ safety tubing and Fits-All™ connector, Pediatric, 10x50pcs
9108MM	93-108MM	Oxygen Mask, High Concentration Non-Rebreather, 2.1m oxygen No-Crush™ safety tubing and Fits-All™ connector, Adult, 10x50pcs