

URGENT FIELD SAFETY NOTICE FND USERS

Commercial name: Various Unomedical High Concentration Oxygen Masks (see Attachment 1

for full details)

Issue Date: 10th May 2017

REF No: See Attachment 1

LOT No: See Attachment 1

FSCA ID: 2017-001

Type of action: Recall / Product Disposal

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'.

FSCA Ref: 2017-001 (add Recall ID) Page 1 of 8



Advice on action to be taken by end user.

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

- 1. Please stop the use of all affected devices as defined in this document.
- 2. Ensure that all affected devices in stock are quarantined.
- 3. Check stock and complete the enclosed 'Recall Response Form for END USERS' which should be forwarded to your distributor **as soon as possible**.
- 4. Contact your distributor to arrange return of affected products, if applicable, 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.

PLEASE PROVIDE A COMPLETED RESPONSE AS SOON AS POSSIBLE.

Contact reference person relating to this letter: (distributor to complete)
Name:
Position:
Address:
Tel:
Fax:
E-mail:

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:

Name Duncan Rowley	Title Director, Regulatory Affairs and Quality Assurance, EMEA	Address ConvaTec Limited, First Avenue, Deeside Industrial Park, Deeside, CH5 2NU, U.K.	
<u>Date</u>	5 th May 2017	Signature	

FSCA Ref: 2017-001 (add Recall ID) Page 2 of 8



Regional contact person for this Field Safety Corrective Action:

Belgium / Estonia / France / Germany / Israel / Jordan / Netherlands / Rwanda / 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

Italy

Tel: 800500190

Email: clienti.convatec@convatec.com

<u>Malta</u>

Tel: +356 7944 7497 Email: ian@ipl.com.mt

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

FSCA Ref: 2017-001 (add Recall ID) Page 3 of 8



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

Consignee of the device:						
Consignee Name:						
Consignee Ad	dress:					
The following H	ligh Concentr	ation Oxvaen Ma	asks have bee	n distribut	ed to your facility:	
Product Code /		AP Code	LOT No.		Quantity Delivered (pieces)	
Please answer each of the following. 1. We have NO affected product. 2. We have the following affected product and are following the instructions given by the distributor: Record quantity (pieces) for each LOT:						
LOT No.	Units on Hand	LOT No.	Units on Hand	LOT	No. Units on Hand	

FSCA Ref: 2015-03 (add Recall ID) Page 4 of 8



FORM Completed and Returned From:

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

FSCA Ref: 2015-03 (add Recall ID)



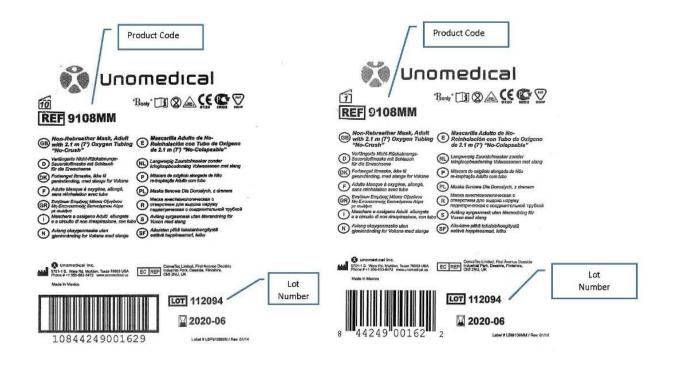
Attachment 1: Product Codes & Lot Numbers affected

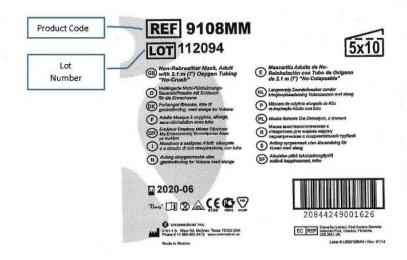
Product Code / REF No.	SAP Code	Description	LOT No's.
104MM	104MM 1302097 Rebreathing mask, Reservoir bag, wi		105631
106MM	1702436	Oxygen Mask, Adult High Concentration Non- Rebreather 2.1 m (7') Oxygen Tubing	100733, 104106, 104798, 100721, 109824
108-E	1300168	Non-Rebreather Oxygen Mask, Adult High 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

FSCA Ref: 2015-03 (add Recall ID) Page 6 of 8



Attachment 2: Example Package Labeling





FSCA Ref: 2015-03 (add Recall ID) Page 7 of 8



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	NEW	NEW
Product Code /	Product Code /	Product Description
REF No.	REF No.	
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

FSCA Ref: 2015-03 (add Recall ID) Page 8 of 8