

**Notice Information: - Advisory
13 June 2011**

Part 1. Product Information

- a) Title: Millennium Oxygen Concentrator
- b) Product Name/Type: Millennium Oxygen Concentrator
- c) Authorisation Number: IMB Safety Notice: SN2011(12)
- d) Manufacturer/Supplier: Philips Respironics

Part 2. Target Audience

- a) Target Audience:
- Hospital CEOs
 - Community Care Managers
 - Community Therapists
 - Health Visitors
 - Carers
 - Risk Managers
 - Loan Store Managers
 - Childrens Disability Services
 - Educational Establishments

Part 3. Problem/Issue

- a) Problem/Issue: Philips Respironics is aware that a small number of Millennium Oxygen Concentrators on the Irish market may not yet have received a capacitor upgrade. The potentially affected population was manufactured between July 2003 and August 2004.

Part 4. Background Information

a) Background Information:

The Irish Medicines Board (IMB) is aware of two incidents involving Millennium Oxygen Concentrators where thermal damage occurred as a result of a failure of a plastic capacitor component. In November 2005, Philips Respironics initiated a corrective action to replace the plastic start/run capacitor with a metal start/run capacitor at the next routine service. There is a possibility that approximately 73 Millennium Oxygen Concentrators, which have not received the replacement metal capacitor, may remain on the Irish market. The potentially affected population of products were manufactured between July 2003 and August 2004.

Millennium Oxygen Concentrators were manufactured with a plastic start/run capacitor from July 2003 through August 2004. During August 2004, Philips Respironics rebranded the Millennium Oxygen Concentrator product and at that time a metal start run capacitor was placed into the concentrator. All Millennium Oxygen Concentrators manufactured since August 2004 have a metal capacitor installed.

Philips Respironics issued a Technical Bulletin in November 2005 to their distributors/authorized service centres of the above-mentioned devices, initiating a corrective action to replace the plastic start/run capacitor with a metal start/run capacitor at the next routine service.

Philips Respironics has advised that they supplied 916 Millennium Oxygen Concentrators to the Irish market. While the vast majority of these devices (>92%) have received the upgraded capacitor, there remain some devices which cannot be located. The IMB acknowledges the efforts made by the manufacturer and their distributors to locate these units. The IMB is issuing this safety notice to ensure all users are aware of the potential problem.

Part 5. Action to be taken

a) Action to be taken:

- 1) Ensure the appropriate personnel are made aware of this notice.
- 2) Identify the location of all Philips Respironics Millennium Concentrators.
- 3) Determine if you / your institution has devices affected by this issue.
- 4) Ensure that corrective action is completed on all affected devices.

Part 6. Enquiries

a) All enquiries should be made to:

Enquiries to the distributors should be addressed to:

MANUFACTURER:

Respironics Deutschland

Gewerbestrasse 17

82211 Herrsching

Germany

Tel: +49 8152 930600

Fax: +49 8152 930618

DISTRIBUTORS:

Air Products Ireland Ltd

18H Rosemount Business Park

Ballycoolin

Dublin 11

Republic of Ireland

Tel: +353 (0) 1 809 1800

LoCall: 1850 24 02 02

Fax: +353 (0) 1 829 3966

Freephone from NI: 0800 3285875

Email: healthie@airproducts.com

Web: www.airproducts.ie/homecare
BOC Healthcare

Blyry Industrial Estate

BOC Healthcare

Blyry Industrial Estate

Athlone

Co. Westmeath

Tel: +353(0) 9064 70910

LoCall: 1890 220202

Fax: +353(0) 9064 74993

Email: healthcareinfo.ie@boc.com

Web: www.bochealthcare.ie

All adverse incidents relating to a medical device should be reported to the:

Irish Medicines Board

Kevin O'Malley House

Earlsfort Centre

Earlsfort Terrace

Dublin 2

Telephone: +353-1-6764971

Fax: +353-1-6344033

E-mail: vigilance@imb.ie

Website: www.imb.ie

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