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NOTICE

Millennium Oxygen Concentrator

IMB Safety Notice: SN2011(12)
Circulation Date: 13 June 2011

MANUFACTURER/SUPPLIER

Philips Respironics

TARGET GROUPS

Hospital CEOs
Community Care Managers
Community Therapists
Health Visitors
Carers
Risk Managers
Loan Store Managers
Childrens Disability Services
Educational Establishments

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.

BACKGROUND

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

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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.

ACTION OR RECOMMENDATIONS

- 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.

ENQUIRIES

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
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