IRISH MEDICINES BOARD
SAFETY NOTICE

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M Series Heated Humidifier

IMB Safety Notice: SN2010(04)
Circulation Date: 17th May 2010

MANUFACTURER/SUPPLIER
Philips Respironics

TARGET GROUPS
Health Board CEOs
Community Care Managers
Community Therapists
Health Visitors
Carers of the Elderly
Risk Managers
Loan Store Managers
Childrens Disability Services
Educational Establishments

ISSUE
Certain Philips Respironics humidifiers may present a risk of potential burn if handled while exhibiting thermal deformation due to a connector failure. This is due to an intermittent connection between the heater plate and the printed circuit board which results in a blinking LED on the humidifier control knob.

BACKGROUND
Philips Respironics issued a field safety notice (FSN) in August 2009 to all their distributors of the above-mentioned devices. Heated Humidifiers shipped from April 2008 through December 2008, and within the serial number range of H001579050 through H002850376 are possibly affected by this action. Please note that not all serial numbers in this range are affected.

The issue may lead to thermal deformation on the bottom of the humidifier enclosure and/or between the CPAP and the humidifier. This could lead to a risk of potential burn when handled. If any such thermal damage is present, ensure you return both the CPAP and the humidifier to your Healthcare Provider/ Distributor.

The Irish Medicines Board (IMB) is aware that several of the suspect humidifiers are on the Irish market and some of the users have not been located by the distributor, Airproducts. The IMB is issuing this safety notice to ensure all users are aware of the potential problem.

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ACTION OR RECOMMENDATIONS

1) Ensure the appropriate personnel are made aware of this notice.
2) Identify the location of all Philips Respironics M Series Heated Humidifiers.
3) Determine if your institution has devices affected by this issue (check the serial numbers).
4) Examine the humidifier control knob for a blinking blue light as shown in the attached field safety notice issued by the manufacturer.
5) Ensure that corrective action is completed on all affected devices.

ENQUIRIES

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
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E-mail: vigilance@imb.ie
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Enquiries to the distributor should be addressed to:
John McEvoy
Airproducts Quality Compliance Manager
UK and Ireland
www.airproducts.ie/homecare

Telephone: Tel: +353-(01)-8091800
E-mail: mcevoyj@airproducts.com