IRISH MEDICINES BOARD

Notice Information: - Advisory
17 May 2010

Part 1. Product Information

a)	Title:	M Series Heated Humidifier
b)	Product Name/Type:	M Series Heated Humidifier
c)	Reference:	SN2010(04)
d)	Manufacturer/Supplier:	Philips Respironics

Part 2. Target Audience

a)	Target Audience:	Health Board CEOs Community Care Managers Community Therapists Health Visitors Carers of the Elderly Risk Managers Loan Store Managers Childrens Disability Services Educational Establishments

Part 3. Problem/Issue

a)	Problem/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.

Part 4. Background Information

a) Background Information:

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.

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 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.

Part 6. Enquiries

a) All enquiries should be made to:

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

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

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