

MEDICAL DEVICE
SAFETY NOTICE

**Profile Respiratory System CR60
and Porta-Neb
IMB Safety Notice: SN2006(02)**

MANUFACTURER / SUPPLIER

Respironics (UK) Limited / Oxygen Care Limited

TARGET GROUPS

Health Board Chief Executives
Community Care Managers
Community Therapists
Health Visitors
Carers of the elderly
Risk Managers
Loan Store Managers
Children's disability services
Special schools
Educational establishments

ISSUE

Incorrectly rated fuses in the IEC socket were fitted to the above devices manufactured between 4th March 2005 and 12th May 2005 due to a vendor issue.

BACKGROUND

An incorrectly rated fuse in the IEC socket (10 amp instead of 1 amp) was fitted to the above devices manufactured between 4th March 2005 and 12th May 2005. The device may overheat and possibly fail if all of the following were to occur:

- (a) There is a problem with the main supply
- (b) An incorrect mains lead is used
- (c) The internal thermal protection fails

The manufacturer has undertaken corrective action of the affected product. They have issued an advisory letter requesting users to check

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fuses and replace them as appropriate in accordance with their instructions.

Oxygen Care Limited has been acting on behalf of the manufacturer Respironics (UK) Limited, following up on the corrective action relating to this device on the Irish market.

The IMB have been advised that approximately 197 devices on the Irish market **still** require modification. Oxygen Care Limited has recently written to remind all customers and to seek their assistance in locating and accessing these devices.

ACTION OR RECOMMENDATIONS

- Advise Oxygen Care Limited of the number and location of all affected devices in your institution.
- Ensure the modification is carried out on all affected devices.

ENQUIRIES

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

Irish Medicines Board
Medical Devices Department
Kevin O'Malley House
Earlsfort Centre
Earlsfort Terrace
Dublin 2

If you have any enquiries, you may contact the Medical Devices Department at:

Telephone: +353-1-6764971
Fax: +353-1-6344033
Email: medicaldevices@imb.ie
Website: www.imb.ie

Enquiries to the manufacturer should be addressed to:

Mr. Karl Goulding
Oxygen Care Limited
Corrig Road
Sandyford Industrial Estate
Dublin 18

Telephone: +353-1-2953421
Fax: +353-1-2953366
Email: k.goulding@oxygen-care.ie

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