

**Notice Information: Medical Devices - Advisory  
14 March 2006**

**Part 1. Product Information**

- a) Title: Profile Respiratory System CR60 and Porta-Neb
- b) Product Name/Type: Profile Respiratory System CR60 and Porta-Neb
- c) Reference: SN2006(02)
- d) Manufacturer/Supplier: Respirationics (UK) Limited / Oxygen Care Limited

**Part 2. Target Audience**

- a) Target Audience: 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

**Part 3. Problem/Issue**

- a) Problem/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.

**Part 4. Background Information**

a) Background Information:

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: There is a problem with the main supply An incorrect mains lead is used 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 fuses and replace them as appropriate in accordance with their instructions. Oxygen Care Limited has been acting on behalf of the manufacturer Respiroics (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.

## Part 5. Action to be taken

a) Action to be taken:

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.

## 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 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 SN2006(02): Profile Respiratory System CR60 and Porta-Neb

## Part 7. Keywords

a) Keywords:

Profile Respiratory System CR60 and Porta-Neb