

Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/28

Issued: 22 June 2004

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION REQUEST	



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

	Section								
Medical Device/Equipment: Peak Expiratory Flow Meter (PFM) all makes.	▶ ①								
Problem: Peak Expiratory Flow Meters (PFMs) manufactured to the new European Standard, EN 13826, are being introduced and may read differently from the traditional Wright PFMs that are being phased out. This change has the potential to cause confusion, but should lead to improvements in diagnosis and treatment of pulmonary disease (e.g. asthma).	▶ ②								
Action by: Respiratory Physicians, Anaesthetists, Respiratory Nurse Specialists, Asthma Nurses, General Practitioners, Practice Nurses, Occupational Health Physicians and Nurses, and Pharmacists.	▶ ③								
Action: <ul style="list-style-type: none"> • Be aware that PFMs manufactured to EN 13826 will be available from 1st September 2004. • Be aware of the differences in peak flow readings between the old and the new PFMs. • Before prescribing or issuing a new EN 13826 PFM, check that a patient's personal best and treatment levels have been re-assessed on the new scale. 	▶ ④								
Distributed by NIAIC to: <table style="width: 100%; border: none;"> <tr> <td style="width: 50%;">Chief Executive of each HSS Board</td> <td style="width: 50%;">General Medical Practitioners</td> </tr> <tr> <td>Chief Executive of each HSS Trust</td> <td>Community Pharmacists</td> </tr> <tr> <td>Chief Executive of each Agency</td> <td>Hospices</td> </tr> <tr> <td>NIAIC Liaison Officers</td> <td></td> </tr> </table>	Chief Executive of each HSS Board	General Medical Practitioners	Chief Executive of each HSS Trust	Community Pharmacists	Chief Executive of each Agency	Hospices	NIAIC Liaison Officers		▶ ⑤
Chief Executive of each HSS Board	General Medical Practitioners								
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NIAIC Liaison Officers									
Contacts Details of NIAIC contacts for technical aspects.	▶ ⑥								
Feedback Requirements to NIAIC None	▶ ⑦								

This Alert is on our web site: <http://www.dhsspsni.gov.uk/niaic>

1. DEVICE/EQUIPMENT:

Hand-held Peak Expiratory Flow Meters (PFMs) for the assessment of pulmonary function and the self-management of asthma.

2. PROBLEM:

Peak Flow Meters manufactured to the new European Standard EN 13826 are being introduced. They will replace the traditional Wright scale and Drug Tariff specification 51, which have been available on NHS prescription since 1990. The new standard is based on absolute flow and should produce peak flow measurements similar to those obtained by conventional spirometry, and a more accurate assessment of peak flow across the entire measurement range.

It has been known for some time that the Wright scale is non-linear and can over-read in the mid-range by up to 30%. This scale has been used for the diagnosis and management of asthma in the UK and Europe since 1959. The non-linearity has not generally caused clinical problems, although in some cases the over-reading of the Wright scale may have falsely reassured patients and their healthcare professionals, so that corticosteroid therapy, whilst appropriate, was not prescribed. This has been the main clinical driver behind the introduction of the new scales and EN 13826.

The new PFMs will be CE marked and identified as complying with EN 13826, i.e. they may be labelled "EN 13826" or "EU scale". Single-patient-use devices will be available on the Drug Tariff from 1st September 2004. Multi-patient-use PFMs, with appropriate cleaning instructions, will also be available from the usual sources, e.g. NHS supply routes, medical equipment suppliers.

It is understood that there is six-week supply chain from the manufacturer through the wholesaler to the pharmacy. It is essential that the stocks of Wright and EN 13826 PFMs are managed correctly to ensure continuity of supply. Wright PFMs should be available up to the end of August, with EN 13826 PFMs available from 1st September. Wright PFMs may still be available after this date, but they may not be reimbursable on NHS prescription.

Practitioners should note that EN 13826 specifies one measurement range from 60 l/min to 800 l/min, which should be suitable for all users. However, low range models may also be available.

The diagnosis of asthma is a clinical judgement based on various symptoms including wheeze, shortness of breath, chest tightness or cough. These tend to be variable, intermittent, worse at night or provoked by triggers including exercise. Variability of peak expiratory flow is also a characteristic of asthma. There are various methods used for assessing the variability.

For further information see:-

"British Guideline on the Management of Asthma" by the British Thoracic Society, Revised edition April 2004, <http://www.brit-thoracic.org.uk/sign/index.htm>

"Peak expiratory flow meter scale changes: implications for patients and health professionals" by Martin R Miller, The Airways Journal 2004; 2 (2): 80-2. <http://www.airwaysextra.com>

BS EN 13826:2003 Peak expiratory flow meters. Available from BSI. <http://www.bsonline.techindex.co.uk>

Drug Tariff available monthly from The Stationery Office or <http://www.ppa.org.uk>

3. ACTION BY:

Respiratory Physicians, Anaesthetists, Respiratory Nurse Specialists, Asthma Nurses, General Practitioners, Practice Nurses, Occupational Health Physicians and Nurses, and Pharmacists.

4. ACTION:

- Healthcare professionals should be aware that:
 - PFM's manufactured to EN 13826 will be available from 1st September 2004;
 - these new PFM's read accurately across the entire measurement range and may give different results to traditional Wright PFM's;
 - this change has the potential to cause confusion in the interpretation of results by all users, and is particularly relevant for patients that have their asthma treated solely on the basis of peak flow measurement.
- Patients with a personalised asthma action plan will need their personal best peak flow re-assessed and their action levels re-calculated when issued with a new EN 13826 PFM. It is recommended that EN 13826 is then recorded on the action plan for reference.
- The Nunn and Gregg patient nomograms (predictive peak flow values) are based on the Wright scale and should not be used with the new EN 13826 PFM's. However, it is expected that new revised predictions will become available.
- PFM's do not need to be changed immediately; a gradual replacement programme over twelve months is recommended – for example when the PFM needs replacing or at the patient's next assessment.

Computer software packages for patient management that contain asthma templates and prescribing information may require updating to reflect the change in PFM scales.

5. ONWARD DISTRIBUTION TO:

Please bring this notice to the attention of all who need to know or be aware of it. This will include distribution to:

- Risk Managers
- Health & Safety Officers/Advisors
- Medical Device & Equipment Co-ordinators
- Clinical Governance Leads
- Medical Directors
- Clinical Directors
- Nurse Directors
- Medical, Nursing and Care Staff
- Accident and Emergency Departments
- Chest Clinics
- Consultant Chest Physicians
- General Physicians
- Trust Pharmacy Managers
- Medical Devices Management Groups
- Occupational Health Departments
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- Outpatient Departments
- Paediatricians
- Respiratory Care Nurse Specialists
- Respiratory Care Technicians
- Ward Managers
- Practice Nurses
- Directors of Public Health
- Independent Health and Social Care Providers – Private Clinics, Residential and Nursing Homes through HSS Board R&I Units
- District Nurses
- Health Visitors
- School Nurses

6. CONTACTS:

Enquiries to the manufacturer should be directed to the name and address marked on the PFM or contained in the accompanying documents.

For information and advice on Asthma please see the following websites:

Asthma UK, <http://www.asthma.org.uk> or contact the Adviceline on Tel: 08457 01 02 03

British Thoracic Society, <http://www.brit-thoracic.org.uk>

General Practice Airway Group, <http://www.gpiag.org>

National Respiratory Training Centre, <http://www.nrtc.org.uk>

6. CONTACTS cont:

Enquires to NIAIC should quote reference number MDEA(NI)2004/28 and be addressed to:
Northern Ireland Adverse Incident Centre (NIAIC)

Health Estates
Estate Policy Directorate
Stoney Road
Dundonald
Belfast BT16 1US

Tel: 028 9052 3868

Fax: 028 9052 3900

Email: NIAIC@dhsspsni.gov.uk

7. FEEDBACK:

None Required



Brian Godfrey
NIAIC Manager

HOW TO REPORT ADVERSE INCIDENTS

Adverse Incidents relating to medical devices, non-medical equipment, plant and buildings should be reported to NIAIC as soon as possible. Advice on how to report is given in MDEA(NI)2004/01. If you are in doubt about how to report incidents, please speak to your liaison officer or contact NIAIC using the telephone number provided. Adverse Incident reporting forms and an on-line reporting facility are available on the NIAIC website at www.dhsspsni.gov.uk/niaic

Heath Estates is an Executive Agency of the Department of Health, Social Services and Public Safety