

Medical Device/Equipment ALERT

Ref. MDEA(NI)2004/60

Issued: 8 December 2004



**NORTHERN
IRELAND
ADVERSE
INCIDENT
CENTRE**

For:

IMMEDIATE ACTION	
ACTION	✓
UPDATE	
INFORMATION REQUEST	

	Section
Medical Device/Equipment: Precision Medical mouth pressure meter (MPM).	▶ ①
Problem: Loose components may be inhaled by patients if incorrectly assembled after cleaning.	▶ ②
Action by: Healthcare professionals responsible for respiratory care including respiratory physicians, clinical scientists, physiotherapists and specialist general practitioners.	▶ ③
Action: <ul style="list-style-type: none"> All Precision Medical reusable mouth pressure meters should be identified. A check should be carried out to ensure that the clips retaining the circular one-way diaphragm valves in the slide valve of each meter are present and securely fitted (see figure in Appendix). Procedures should be updated to ensure that all Precision Medical MPMs are decontaminated after each use in accordance with the revised cleaning instructions (see Appendix). In particular, checks should be made to ensure that the clips retaining the circular one-way diaphragm valves in the slide valve are present and securely fitted. 	▶ ④
Distributed by NIAIC to: Chief Executive of each HSS Board Chief Executive of each HSS Trust Chief Executive of each Agency NIAIC Liaison Officers	▶ ⑤
Contacts Details of supplier contacts, NIAIC for technical and clinical aspects	▶ ⑥
Feedback Requirements to NIAIC None	▶ ⑦

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

1. DEVICE/EQUIPMENT:

Precision Medical reusable mouth pressure meter (MPM) for the assessment of respiratory muscle weakness.

2. PROBLEM:

Precision Medical manufactured a reusable mouth pressure meter (MPM) until 1996. These are used for monitoring patients with chronic obstructive pulmonary disease (COPD) or other complaint affecting the function of the respiratory muscles.

An incident has been reported in which one of the circular one-way diaphragm valves of the MPM's slide valve became loose and was inhaled by the patient. Fortunately, the valve was retrieved when the patient coughed and there was no harm caused on this occasion.

On examination, the plastic clip for retaining the diaphragm valve was missing. It could not be established whether the clip had been inhaled or whether it had not been re-assembled after decontamination following the previous use. As a result of this incident the original cleaning instructions have been made available with an extra emphasis on correct re-assembly.

These instructions have been made available by Ferraris Respiratory Europe Ltd., who purchased the intellectual property rights from Precision Medical back in 1996. This product is now obsolete and there are no spare parts available.

3. ACTION BY:

Healthcare professionals responsible for respiratory care including respiratory physicians, clinical scientists, physiotherapists and specialist general practitioners.

4. ACTION:

All Precision Medical reusable mouth pressure meters should be identified. A check should be carried out to ensure that the clips retaining the circular one-way diaphragm valves in the slide valve of each meter are present and securely fitted (see figure in Appendix).

Procedures should be updated to ensure that all Precision Medical MPMs are decontaminated after each use in accordance with the revised cleaning instructions (see Appendix). In particular, checks should be made to ensure that the clips retaining the circular one-way diaphragm valves in the slide valve are present and securely fitted.

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:

- Liaison Officers
- Clinical Governance Leads
- Consultant Chest Physicians
- Nurse Consultants Respiratory Medicine
- Medical Directors
- Clinical Directors
- Nurse Directors
- Respiratory Physicians
- Respiratory Care Technicians
- Respiratory care nurses and nurse specialists
- Decontamination Leads
- Risk Managers
- Health & Safety Officers/Advisors
- Sterile Services Departments
- Occupational Therapists
- Physiotherapists
- Independent Health and Social Care Providers – Private Clinics through HSS Board R&I Units
- GP Practice managers for onward distribution to General Medical Practitioners where relevant

6. CONTACTS:

Enquiries to the supplier should be addressed to:

Mr Stavros Vassos
Ferraris Respiratory Europe Ltd.
Harforde Court
John Tate Road
Hertford
SG13 7NW

Tel: 01992 526 312

Fax: 01992 526 320

E-mail: s.vassos@fml.ferrarisgroup.com

Enquires to NIAIC should quote reference number MDEA(NI)2004/60 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



Robert Sergeant
NIAIC Operational 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

APPENDIX to MDEA(NI)2004/60

(Page 6 of the user manual)

MOUTH PRESSURE METER CLEANING INSTRUCTIONS

Air flow through the mouthpiece and slide valve assembly is bi-directional and it is recommended that these parts are cleaned between patients.

PROCEDURE – refer to figure 2 in the manual (exploded instrument diagram).

1. Detach the mouthpiece.
2. Unscrew the mouthpiece adaptor and remove the upper airway cover.
3. Detach the sampling tube by gently twisting and pulling the white bayonet fitting on the tube.
4. Unscrew the two black knurled retaining nuts located on the outer ring of the airway assembly.
5. Lift the airway assembly off its screw mountings, dismantle and immerse all airway parts including the mouthpiece and adaptor in a suitable cold sterilizing solution (such as Milton) for the prescribed time.
6. Thoroughly rinse and dry the valve, making sure the clips retaining the circular one way diaphragm valves in the slide valve are present and are securely fitted. No attempt should be made to re-assemble or use the instrument if the clips are not present or are not securely fitted. Ensure that the bayonet coupling is completely dry before re-assembling the unit.
7. Re-assembly is the reverse of the above – do not over tighten the retaining nuts, as this will cause the slide valve to stick.

WARNING

DO NOT AUTOCLAVE EITHER THE MOUTHPIECES OR THE AIRWAY ASSEMBLY.
DO NOT USE THE INSTRUMENT IF THE ONE WAY DIAPHRAGM VALVE RETAINING CLIPS ARE MISSING OR BROKEN.

APPENDIX to MDEA(NI)2004/60

(Page 7 of the user manual)

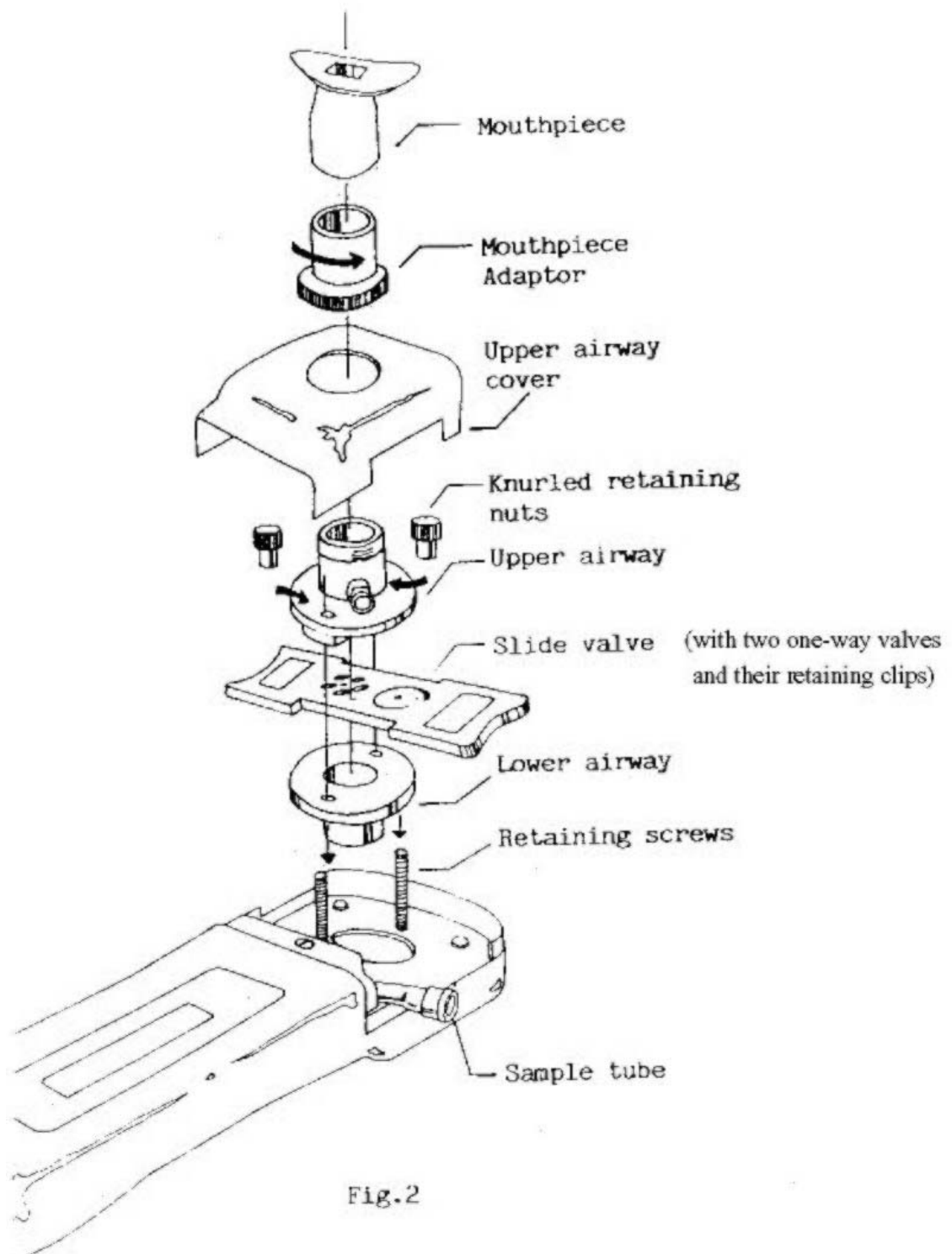


Fig.2