

Australian/New Zealand Standard

**Respiratory therapy equipment—
Peak expiratory flow meters**

AS/NZS 4237:1994

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The following interests are represented on Committee HT/7:

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Australian and New Zealand College of Anaesthetists
Australian Chamber of Commerce and Industry
Australian Society of Anaesthetists
Commonwealth Department of Human Services and Health
Department of Health and Community Services, Vic.
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Health Department, W.A.
Medical Industry Association of Australia
Metal Trades Industry Association of Australia
Ministry of Commerce, N.Z.
New Zealand Electrical and Electronic Manufacturers Federation
Queensland Health
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Alfred Hospital, Melbourne, Vic.
Asthma Foundation of Victoria
Manufacturing interests
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Respiratory therapy equipment— Peak expiratory flow meters

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PREFACE

This Standard was prepared by the Joint Australia/New Zealand Standards Committee HT/7 on Anaesthetic Equipment and Medical Breathing Machines. It is issued as a Joint Standard under the terms of the Active Cooperation Agreement between Standards Australia and Standards New Zealand.

The Standard was requested by the Department of Health, Housing and Community Services (Commonwealth of Australia) which was concerned about the lack of accuracy of some peak expiratory flow meters on the market. The objective of this Standard, therefore, is to provide users with peak expiratory flow meters that give an accurate output of their contents, so that user safety is not compromised.

Requirements for mouthpieces have been considered as not necessary provided that when the peak expiratory flow meter is tested with the appropriate mouthpiece, the requirements of the Standard are met.

The term ‘normative’ has been used in this Standard to define the application of the appendix to which it applies. A ‘normative’ appendix is an integral part of a Standard.

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STANDARDS AUSTRALIA/STANDARDS NEW ZEALAND

Australian/New Zealand Standard**Respiratory therapy equipment—Peak expiratory flow meters**

1 SCOPE This Standard sets out the requirements for simple mechanical, electro-mechanical and electrical portable hand-held peak expiratory flow meters (PEFM) for self-monitoring of peak expiratory flow rate.

2 REFERENCED DOCUMENT The following document is referred to in this Standard: Therapeutic Goods Order (TGO) No. 37, General requirements for labels for therapeutic devices (Commonwealth of Australia).

3 DEFINITIONS For the purpose of this Standard, the definitions below apply.

3.1 Low range—the span of values within which the PEFR can be measured at the specified accuracy in children or in adults with substantially reduced peak flow.

3.2 Measurement range—the span of values within which the PEFR can be measured in adults and children at the specified accuracy.

3.3 Peak expiratory flow meter (PEFM)—a hand-held portable instrument, including the mouthpiece, for measurement of peak expiratory flow rate (PEFR) to be used by the patient for self-monitoring.

3.4 Peak expiratory flow rate (PEFR)—maximum flow rate measured at the mouth as a result of maximal expiratory effort immediately following maximal inspiratory effort.

3.5 Set peak flow rate—the peak flow rate which an air flow source is set to deliver.

3.6 Standard range—the span of values within which the PEFR can be measured in adults with normal or non-severely restricted peak flow.

4 REQUIREMENTS

4.1 Accuracy When measured in accordance with Appendix A, the peak expiratory flow meter shall, over its full range, have an absolute error of ± 15 L/min or $\pm 7.5\%$ of the reading, whichever is greater.

4.2 Peak expiratory flow meter output repeatability When tested in accordance with Appendix A, the repeatability of the PEFM at any set peak flow rate in the measurement range shall not vary by more than 20 L/min.

4.3 PEFR measurement ranges

4.3.1 Standard range The lower limit for measurement of PEFR shall be less than 150 L/min and the upper limit shall be greater than 700 L/min but less than 850 L/min.

4.3.2 Low range The lower limit for measurement of PEFR shall be less than 60 L/min, and the upper limit shall be greater than 275 L/min but less than 375 L/min.

4.4 Scale

4.4.1 Marking The scale shall be marked in litres per minute.

4.4.2 Graduation lines The distance between any two adjacent graduation lines shall represent a peak flow of not greater than 20 L/min.

NOTE: This requirement does not apply to digital meters.

4.4.3 Numbering The figures with which a graduation line is numbered shall be upright, distinct, legible and appear at intervals no greater than 50 L/min.

NOTE: This requirement does not apply to digital meters.