

Australian/New Zealand Standard

Respiratory therapy equipment— Jet nebulizers and jet nebulizer air pumps

AS/NZS 4236:1994

This Joint Australian/New Zealand Standard was prepared by Joint Technical Committee HT/7, Anaesthetic Equipment and Medical Breathing Machines. It was approved on behalf of the Council of Standards Australia on 7 July 1994 and on behalf of the Council of Standards New Zealand on 12 May 1994. It was published on 19 September 1994.

The following interests are represented on Committee HT/7:

Auckland Healthcare
Australian and New Zealand College of Anaesthetists
Australian Chamber of Commerce and Industry
Australian Society of Anaesthetists
Commonwealth Department of Human Services and Health (Australia)
Department of Health and Community Services, Vic.
Department of Health, N.S.W.
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
South Australian Health Commission

Additional interests participating in preparation of Standard:

Alfred Hospital, Melbourne, Vic.
Asthma Foundation of Victoria
Manufacturing interests
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Royal Prince Alfred Hospital, N.S.W.

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand 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 Commonwealth Department of Human Services and Health (Australia) which was concerned about the effectiveness of some jet nebulizers on the market. The objective of this Standard, therefore, is to provide users with a safe and effective jet nebulizer and jet nebulizer air pump.

The possible veterinary applications for many of these devices has not been considered and, furthermore, no attempt has been made to delineate the classes and specific types of nebulizers; rather the Standard focuses on safety related performance aspects of the jet nebulizer.

Recent studies have indicated that evaporative losses may affect the delivery dose of the drug, and the degree of this effect may vary between nebulizer types.

This Standard introduces the concept of minimum fill volume to ensure that sufficient of the prescribed drug dosage is delivered within a clinically acceptable period. Normal prescribing practice often ignores the effects of residual volume, resulting in under-dosage.

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—
Jet nebulizers and jet nebulizer air pumps

1 SCOPE This Standard specifies performance and safety requirements for jet nebulizers and associated portable air pumps used in respiratory drug therapy.

Requirements for atomizers are not dealt with in this Standard.

2 REFERENCED DOCUMENTS The following documents are referred to in this Standard:

AS

1081 Acoustics—Measurement of airborne noise emitted by rotating electrical machinery

1081.2 Method 2: Survey method

3200 Approval and test specification—Electromedical equipment—General requirements

3200.1 Part 1: General requirements for safety

United States Pharmacopoeia (USP), XXII (1990) Containers, Monograph 661

British Pharmacopoeia (BP), 1988, Vols I & II

European Pharmacopoeia (EP) 2nd Edition

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

3.1 Continuous operation—operation of the system without stopping.

3.2 Jet nebulizer—device designed to add bulk liquid (including water) to the inspired air in the form of small particles.

3.3 Jet nebulizer air pump—compressor delivering pressurized oil-free air.

3.4 Jet nebulizer outlet—the apparatus port from which aerosol flows.

3.5 Jet nebulizer useful device life—period in which the mass median diameter (MMD) of the delivered particles of the device in use is within 10% of the MMD of the delivered particles of the new device at the recommended airflow.

3.6 Mass median diameter (MMD)—size of particles (aerosol mass), in micrometres, below which 50% of the total mass of particles generated are contained.

3.7 Non-spill volume—volume remaining in the jet nebulizer after it is inverted to allow maximum spillage.

3.8 Recommended airflow—airflow at the outlet of the nebulizer, recommended by the manufacturer to achieve the optimum MMD.

3.9 Reservoir—portion of a device that contains the bulk liquid to be added to the gas.

3.10 Residual volume—volume of solution remaining in the reservoir that cannot be nebulized.

3.11 Single use only device—device intended to be used once and then discarded.