

Respiratory therapy equipment —

Part 3: Specification for gas-powered nebulizers for the delivery of drugs

Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care and Environment Sector Board to Technical Committee HCC/44, upon which the following bodies were represented:

- Association of Anaesthetists of Great Britain and Ireland
- Association of British Health-care Industries
- Association of Veterinary Anaesthetists of Great Britain and Ireland
- British Anaesthetic and Respiratory Equipment Manufacturers' Association
- Department of Health
- Medical Sterile Products Association

The following bodies were also represented in the drafting of the standard, through subcommittees and panels.

- Guild of Hospital Pharmacists
- Coopted members

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Contents

	Page
Committees responsible	Inside front cover
Foreword	ii
1 Scope	1
2 References	1
3 Definitions	1
4 General	1
5 Connections	2
6 Marking	2
7 Information to be supplied by the manufacturer	2
Annex A (normative) Methods of test	3
Figure A.1 — Typical test apparatus for determination of aerosol output	4
Figure A.2 — Typical test apparatus for use with laser diffraction particle sizer	6
List of references	Inside back cover

Foreword

This Part of BS 7711 has been prepared under the direction of the Health Care and Environment Sector Board. It relates to gas-powered nebulizers that are directly in contact with respirable gases and used for the delivery of drugs as part of respiratory therapy. The efficiency of these devices depends largely on the proportion of their output which is of suitable size to penetrate the respiratory system of the patient to the required extent [1], [2], [3].

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Summary of pages

This document comprises a front cover, an inside front cover, pages i and ii, pages 1 to 8, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

1 Scope

This Part of BS 7711 specifies minimum performance and safety requirements for gas-powered nebulizers used for the delivery of drugs to patients through the respiratory system. Test methods for measuring performance are given in Annex A.

The standard does not include humidifiers operating on the nebulizing principle, nebulizers using ultrasonic power or devices for the delivery of drugs by dry powder inhalation.

2 References

2.1 Normative references

This Part of BS 7711 incorporates, by dated or undated reference, provisions from other publications. These normative references are made at the appropriate places in the text and the cited publications are listed on the inside back cover. For dated references, only the edition cited applies; any subsequent amendments to or revisions of the cited publication apply to this Part of BS 7711 only when incorporated in the reference by amendment or revision. For undated references, the latest edition of the cited publication applies, together with any amendments.

2.2 Informative references

This Part of BS 7711 refers to other publications that provide information or guidance. Editions of these publications current at the time of issue of this standard are listed on the inside back cover, but reference should be made to the latest editions.

3 Definitions

For the purposes of this Part of BS 7711, the following definitions apply.

3.1

gas-powered nebulizer

device which converts a liquid into an aerosol by means of compressed gas

NOTE Hereinafter referred to as a nebulizer.

3.2

liquid container

that part of the nebulizer which contains the liquid for nebulization

3.3

maximum fill volume

maximum volume of liquid in the liquid container during normal operation when the nebulizer is filled to the maximum filling level

3.4

residual volume

volume of liquid remaining in the liquid container after continuous nebulization has ceased

3.5

aerosol

suspension of liquid particles in a gas

3.6

aerosol output

rate of production of particles in aerosol form by the nebulizer, expressed in mg/min

3.7

respirable particles

aerosol particles 5 µm or less in diameter

NOTE Current opinion is that deposition of particles of aerosol from nebulizers is as follows:

- a) tracheobronchial deposition: particles of 2 µm to 5 µm diameter;
- b) alveolar deposition: particles of less than 2 µm diameter.

3.8

respirable fraction

proportion of respirable particles in the aerosol output, expressed as a percentage by mass

3.9

respirable output

rate of production of respirable particles by the nebulizer, expressed in mg/min

NOTE Respirable output = aerosol output × respirable fraction.

4 General

NOTE 1 The nebulizer should be sufficiently robust to withstand reasonable mechanical stresses and to resist degradation by vapours or medicaments which are not specifically prohibited by the manufacturer.

NOTE 2 In clinical use drugs will be dispensed into the nebulizer by volume. For the purpose of laboratory tests, however, gravimetric methods are preferred and the requirements specified in this Part of BS 7711 have been expressed in gravimetric units. The solutions used have densities close to 1 g/ml.

4.1 Testing

The test methods given in Annex A or other test methods which have been demonstrated to be of comparable accuracy shall be used. In case of dispute the test methods given in Annex A shall be used.

In either case the test report shall give the information listed in A.6.