

Specification for

Oxygen concentrators for use with medical gas pipeline systems

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Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) 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

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Standards Board and comes into effect on 15 March 1993

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National foreword

This British Standard has been prepared under the direction of the Health Care Standards Policy Committee and is identical with ISO 10083 *Oxygen concentrators for use with medical gas pipeline systems*, prepared by Technical Committee ISO/TC 121, Anaesthetic and respiratory equipment, of the International Organization for Standardization (ISO).

Attention is drawn to BS 5724-2.23:1989, which specifies requirements for the safety of oxygen concentrators not used with medical gas pipeline systems.

Cross-references. The Technical Committee has reviewed the provisions of ISO 5145:1990, ISO 7396:1987 and IEC 364-2:1970, to which normative reference is made in the text, and has decided that they are acceptable for use in conjunction with this British Standard.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

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.

Introduction

The purpose of this International Standard is to specify performance and safety requirements for oxygen concentrators connected to medical gas pipeline systems. The basic requirement of the oxygen concentrator is to provide a safe, reliable local source of oxygen-enriched air of sufficiently high oxygen concentration to supply medical needs. Special consideration has to be given to providing a safe system with adequate reserves since life support is dependent on a non-failing supply.

There is more than one way of achieving a high concentration of oxygen. This International Standard specifies requirements for the molecular sieve type of oxygen concentrator, also known as a pressure swing adsorber (PSA). Other types will be included when they are at a stage where they can be applied practically to hospital pipeline systems.

This International Standard does not purport to guarantee the suitability of the product gas for all clinical procedures, nor does it necessarily imply cost advantages over other methods of oxygen supply; it does, however, lay down the minimum requirements for those circumstances in which hospital authorities choose this method of supply.

1 Scope

This International Standard specifies requirements for an oxygen concentrator system including a reserve supply, for use with medical gas pipeline systems which comply with ISO 7396, comprising a pressure swing adsorber (PSA) system and its source of air supply. It includes requirements for safety, quality, purity and availability of supply. It also specifies the air source for oxygen concentrators.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions or this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 407:1991, *Small medical gas cylinders — Pin-index yoke-type valve connections*.

ISO 5145:1990, *Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning*.

ISO 7396:1987, *Non-flammable medical gas pipeline systems*.

IEC 364-2:1970, *Electrical installations of buildings — Part 2: Fundamental principles*.

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1

(non-flammable medical gas) pipeline system

central supply system with control equipment, a pipeline distribution system and terminal units at the point where non-flammable medical gases may be delivered

3.2

medical oxygen concentrator

system, with dedicated air compressors, comprising molecular sieve devices by means of which oxygen-enriched air is produced from ambient air

3.3

primary supply

that part of the medical oxygen concentrator system which supplies the pipeline distribution system

3.4

secondary supply

that part of the medical oxygen concentrator system which automatically supplies the pipeline distribution system when the primary supply fails

3.5

reserve supply

that part of the medical oxygen concentrator system, which operates automatically, to supply the pipeline distribution system in the event of a failure of the primary and secondary supplies

3.6

control equipment

those items which are necessary to maintain the set pressures and the oxygen concentration within the control limits, such as pressure regulators, oxygen analysers, relief valves, alarm initiators, manual and automatic valves

3.7

pipeline distribution system

that part of a pipeline system linking the source of supply to the terminal units, including any necessary branch isolation valves and any additional line pressure regulators required to reduce further the pressure in a part of the distribution system, downstream of the source of supply