

SUMMARY OF ISO 8359 OXYGEN CONCENTRATORS FOR MEDICAL USE IN PAEDIATRIC WARDS

David Peel, DPhil

Ashdown Consultants, Hartfield, UK

Trevor Duke, MD FRACP

Centre for International Child Health, University of Melbourne Department of Paediatrics,
MCRI, Royal Children's Hospital, Parkville, Victoria, Australia, and School of Medicine &
Health Sciences, University of Papua New Guinea

Rami Subhi, BMed Sci

Centre for International Child Health, University of Melbourne Department of Paediatrics,
MCRI, Royal Children's Hospital, Parkville, Victoria, Australia

TABLE OF CONTENTS

SUMMARY OF ISO 8359 OXYGEN CONCENTRATORS FOR MEDICAL USE	3
THE RELEVANCE OF ISO 8359 TO OXYGEN CONCENTRATORS FOR PAEDIATRIC USE	5
RECOMMENDATIONS FOR PURCHASING AN OXYGEN CONCENTRATOR	8

SUMMARY OF ISO 8359 OXYGEN CONCENTRATORS FOR MEDICAL USE – SAFETY REQUIREMENTS

This International Standard outlines the safety requirements for oxygen concentrators used for medical purposes. It is a 30 page document which has remained essentially unchanged since it was first published in 1988, and has been reconfirmed at regular intervals by the committee which is responsible for it. The document is in a standard format based on the General Standard for Medical Electrical Equipment (ISO 60601). Many clauses in ISO 8359 simply say that the appropriate clause of the General Standard does or does not apply. These are typical electrical safety requirements.

The clauses of ISO 8359 outline requirements for each of the following:

- **Technical descriptions and definitions** of standard terms, including an important new definition: Oxygen Concentrator Status Indicator (OCSI) – a device which indicates when the proportion of oxygen in the product gas is at an abnormal level
- **Identification, markings and documents**
 - Markings are required to include a warning: “No smoking or naked flames” and a statement: “Use no oil or grease”.
 - Specification for a humidifier and at least one set of oxygen administration accessories
 - A technical description that includes:
 - A table showing values of oxygen concentration as a function of flow rate
 - The maximum outlet pressure
 - The maximum A-weighted sound pressure in decibels
 - The maximum recommended flow rate
 - The threshold of oxygen concentration below which the OCSI gives an indication of abnormal concentration in the product gas
 - Temperature range within which the oxygen concentrator is intended to operate
 - Variation of oxygen concentration over the altitude range 0 to 4000 metres above sea level
- **Vibration and noise**
 - The maximum sound pressure level should not exceed 60dB under the specified test conditions
- **Excessive temperatures and fire prevention**
 - The gas temperature at the oxygen concentrator outlet should not exceed 46° C under the specified test conditions
 - Standard tests for fire prevention are applied under normal and single fault conditions

- **Accuracy of operating data**
 - Flow indicators should be accurate to +/- 10% of the produced flow
 - Oxygen concentration should be within +/-3% of the stated value at 2L/min flow
 - Oxygen concentration should be stable within +/-3% over 8 hours at maximum flow rate
 - Outlet pressure should be within +/-10% of the stated value
 - The flow rate should be within +/- 10% of the maximum recommended flow rate when a back pressure of 7kPa is applied
- **Protection against hazardous output.** The following components are required to be fitted:
 - A flow control device
 - A filter retaining 10 micro-metre particles between the oxygen concentrating elements and the concentrator outlet
 - An oxygen concentration status indicator (OCSI) which indicates when the oxygen concentration falls below 82%
 - Indicators of mechanical and electrical malfunction for specified faults
 - A non-resettable elapsed time indicator
 - An auditory alarm to indicate loss of mains power
 - All auditory indicators shall comply with ISO 9703-2

In summary the requirements ensure that oxygen concentrators that comply with the Standard will be safe to operate. The Standard also requires user and service manuals containing appropriate technical descriptions together with a comprehensive list of warnings to be provided.

The Standard includes an annex that outlines the testing apparatus and methodology for measuring each of the relevant requirements.

THE RELEVANCE OF ISO 8359 TO OXYGEN CONCENTRATORS FOR PAEDIATRIC USE

SCOPE

Oxygen concentrators are intended as a domiciliary source of continuous oxygen supply. Due to their widespread use, they are cheap and reliable, and have been shown to be adaptable to children's wards in less-developed countries, where they can be installed to deliver oxygen to multiple patients at the same time. However, the scope of ISO 8359 states that, "this International Standard does not apply to oxygen concentrators intended to supply gas to several patients." This means that oxygen concentrators which comply with ISO 8359 may not necessarily be adaptable for multi-patient use in paediatric wards. Nevertheless ISO 8359 is fundamentally relevant to this application because it defines many important performance aspects of concentrator function.

COMPLIANCE WITH ISO 8359

Compliance with ISO 8359 is voluntary, and there is no legal requirement in most countries that oxygen concentrators shall comply with this Standard. The process of CE marking used in the European Community requires that manufacturers shall provide documentation which shows how each model complies with ISO 8359. There are no fixed criteria for compliance on many aspects of the Standard so that there are substantial variations in the performance of different models

The process of checking whether or not any device actually complies with the European requirements is administered by a large number of organisations (Notified Bodies) which do not necessarily apply the same level of expertise to their evaluations. For these reasons the level of compliance with ISO 8359 may vary.

GENERAL REQUIREMENTS

The general requirements for the electrical safety of medical devices are essential for safe use in a hospital environment. These aspects of ISO 8359 apply in full for paediatric use.

PARTICULAR REQUIREMENTS

The particular requirements listed above in the summary of the content of ISO 8359 are all relevant to paediatric use so that the details of the construction and performance of each model can be evaluated by comparison to this data. Information provided by the manufacturer on all the relevant parameters should be considered before purchase. There are significant differences in the performance

between different models, notably in the temperature range within which the concentrator is intended to operate.

In general the specification and supply of a humidifier may be less important when nasal prongs and catheters (but not nasopharyngeal catheters) are used for oxygen delivery to children.

Other factors relevant to paediatric use

There are several additional aspects of the performance and specification of concentrators intended for paediatric use which are not considered in ISO 8359. Some of these are of a general nature and others relate to the specific requirements for paediatric use.

General factors

- **Flow:** there must be a requirement to state the maximum flow at which a concentration of at least 90% will be achieved, such that the performance of different models can be compared. This should take into account the tolerance of +/- 3% which is permitted in ISO 8359
- **Relative humidity:** the range of relative humidity within which the oxygen concentrator is intended to operate must be taken into account together with the temperature range
- **Durability:** a minimum life of 5 years continuous operation is needed for equipment which will be used in a healthcare facility
- **Maintenance requirements:** the frequency of specified maintenance activities must be stated
- **Cost of spare parts:** the estimated cost of specified and predictable spare parts must be stated for 40,000 running hours of use
- **Efficiency:** an index of the efficiency of operation is needed for comparison of the effectiveness of different models. The index proposed is the number of litres of oxygen of >90% concentration produced at specified ambient conditions (40 °C and 95% relative humidity) per kilowatt hour

Specific requirements

- A means to deliver controlled, measured flows to several patients at the same time, for a defined additional cost. This can be achieved using a flow-splitter or multiple flow meters.

- **Delivery equipment:** nasal prongs are the optimal means of final delivery of oxygen to the patient. Where these are not available, nasal catheters are an alternative. Means must be sought to provide these devices at an acceptable cost probably by developing a locally approved method of cleaning the nasal prongs. Single use prongs for each patient are likely to cost more than a concentrator over a 5 year period. Since the delivery equipment is an essential component for the effective use of concentrators it is important to establish a supply of sufficient quantities at the time of purchase of the concentrator. These are likely to be from a different manufacturer
- **Fire prevention:** means shall be provided to prevent the spread of fire from the delivery equipment to the oxygen concentrator (eg. Fire-break device)

RECOMMENDATIONS FOR PURCHASING AN OXYGEN CONCENTRATOR FOR USE IN PAEDIATRIC WARDS

The following are the recommended minimum specifications for an oxygen concentrator intended to be used in a paediatric ward. Please note that there are currently very few oxygen concentrators which meet all these specifications.

- Certified compliance with ISO 8359, plus
- 5L/min of >90% oxygen at 40 °C and 90% relative humidity
- Fitting of an oxygen concentration indicator set to alarm at < 82% O₂ concentration
- Maximum altitude for the specified performance to be at least 2000 metres
- 5 years warranty (at a defined cost)
- Spare parts and consumables for 5 years listed at a defined cost
- Efficiency not less than 850 Litres of >90% O₂ per kilowatt hour
- Means for delivery of controlled flows to be defined with the cost identified.
- Provision of sufficient nasal prongs of appropriate sizes for 5 years with the cost identified
- Provision of fire breaks to prevent the spread of oxygen fires to the concentrator

SUMMARY

The requirements for an oxygen concentrator intended to be used for the treatment of hypoxia in a paediatric ward are significantly more complex than the requirements of ISO 8359. This Standard does, however, set a baseline performance which is a useful starting point for the procurement of suitable concentrators. All aspects of the specification recommended above are important for paediatric use, but the details of the performance of each model need to be carefully scrutinised