INTERNATIONAL STANDARD

ISO 8359

Second edition
1996-12-15

AMENDMENT 1
2012-07-01

Oxygen concentrators for medical use — Safety requirements

AMENDMENT 1

Concentrateurs d'oxygène à usage médical — Prescriptions de sécurité

AMENDEMENT 1

Reference number
ISO 8359:1996/Amd.1:2012(E)

COPYRIGHT PROTECTED DOCUMENT

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

Amendment 1 to ISO 8359:1996 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

This amendment was prepared to address new information regarding the role of oxygen concentrators in accelerating fires in the home that have been caused by patients smoking while undergoing oxygen therapy. Although these changes cannot prevent such fires, it is hoped that the severity of such fires can be reduced by these changes.

Oxygen concentrators for medical use — Safety requirements

AMENDMENT 1

Page 4, 1.7

Add the following additional item to the bullet starting “In **6.8.2 a)**”:

12) statement to the effect that the accessories set-up used to deliver oxygen to the patient shall include a means to reduce the propagation of fire for the safety of the patient.

NOTE This can be achieved by incorporating a means to stop the flow of gas from the oxygen concentrator or humidifier, if provided, in the presence of fire.

Page 17, 10.3

Add the following subclauses:

56.12 Additional requirements for fire mitigation

The operator-accessible oxygen concentrator outlet shall include a means to prevent the propagation of fire back through the oxygen concentrator outlet in the case that the accessory becomes ignited. This means shall not be detachable by the operator without the use of a tool.

NOTE Where the oxygen concentrator includes an integral humidifier, the humidifier outlet includes the means.

Check compliance by inspection and the following test.

1) *For an oxygen concentrator capable of delivering oxygen in a continuous mode, set the oxygen concentrator to the maximum continuous flow rate of normal use, with accessory connection tubing of approximately 2 m in length connected to the oxygen concentrator outlet connector. For an oxygen concentrator not capable of delivering oxygen in a continuous mode, go to step 5.*

2) *Wait for steady-state conditions to be achieved.*

3) *Ignite the accessory connection tubing or cannula at the end opposite to the oxygen concentrator outlet connector.*

4) *Observe the fire propagating along the connecting tubing towards the oxygen concentrator and verify that the fire is not propagating back through the oxygen concentrator outlet connector into the oxygen concentrator.*

5) *For an oxygen concentrator equipped with a conserving device, set the oxygen concentrator to the maximum demand flow rate setting of normal use and a triggering frequency of 20 breath/min. Perform steps 2) to 4).*

56.13 Fire mitigation accessories

The accessories set-up that delivers gas to the patient from an oxygen concentrator shall include a means to stop the flow of gas towards the patient in the case that the accessory becomes ignited. The means of protection should be located as close to the patient as reasonably practicable.

NOTE 1 This means is intended to prevent the propagation of fire towards the equipment from the accessory.

NOTE 2 Additional fire prevention requirements are specified in subclause 56.12.

EXAMPLE The means to stop the flow of gas towards the patient is located at the junction of the nasal cannula and the oxygen supply tubing.

Check compliance by inspection and the following test.

1) *Connect the accessory under test to the outlet connector of an oxygen source.*

2) *Set the oxygen source to deliver a continuous flow rate of 10 l/min ± 1 l/min through the accessory.*

3) *Ignite the accessory under test at the end opposite the outlet connector of the oxygen source.*

4) *Observe the fire propagating along the accessory towards the oxygen source and verify that the flow of oxygen is stopped when the fire reaches the means to stop the flow, and that the fire is not propagated through the means towards the oxygen source.*

ICS 11.040.10

Price based on 2 pages