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Dihalna oprema za zdravljenje – 3. del: Vhodne naprave za zrak

Respiratory therapy equipment - Part 3: Air entrainment devices

Atemtherapiegeräte - Teil 3: Luftbeimischgeräte

Appareils de thérapie respiratoire - Partie 3: Dispositifs d'entrainement d'air

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Respiratory therapy equipment - Part 3: Air entrainment devices

Atemtherapiegeräte - Teil 3: Sauerstoffanreicherungsgeräte

This European Standard was approved by CEN on 7 April 2001.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Foreword

This European Standard has been prepared by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by November 2001, and conflicting national standards shall be withdrawn at the latest by November 2001.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

This European Standard applies to respiratory therapy equipment and has been prepared in three parts. This Part addresses air entrainment devices; part 1 and part 2 address respectively nebulizing systems and tubing and connectors.

Annex A is normative and forms part of this European Standard.

Annexes B, C and ZA are for information only.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

1 Scope

This part of this European Standard specifies minimum performance and safety requirements for air entrainment devices used for delivery of a designated oxygen concentration to patients. It gives a test method to check the oxygen concentration in the air/oxygen mixture generated by the air entrainment device.

It also specifies marking requirements and gives an optional system of colour coding to assist the user to identify the designated oxygen concentration.

This standard does not cover air entrainment devices which are integral with medical devices specified in other standards e.g. emergency lung ventilators, humidifiers, nebulizers, etc.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN 738-1, *Pressure regulators for use with medical gases – Part 1 : Pressure regulators and pressure regulators with flow metering devices.*

EN 980, *Graphical symbols for use in the labelling of medical devices.*

EN 1041, *Information supplied by the manufacturer with medical devices.*

prEN 13159, *Compatibility of medical equipment with oxygen.*

EN ISO 4135, *Anaesthetics and respiratory equipment – Vocabulary.*

3 Terms and definition

For the purposes of this part of this European Standard, terms and definitions given in EN ISO 4135 and the following term and definition apply.

3.1 Air entrainment device

Device consisting of a jet orifice (to which the oxygen supply is connected) adjacent to a series of air entrainment ports, the distal end of the device being designed for connection to an oxygen delivery system supplying a patient.

NOTE These devices are sometimes described as Venturi devices. This term has been avoided as very few actually use the venturi principle.

4 Oxygen supply

The device shall be designed to operate with an oxygen supply controlled by a flowmeter control valve capable of delivering at least 15 l/min of oxygen and complying with EN 738-1 and prEN 13159.

5 Connections

5.1 Oxygen supply inlet

The inlet for oxygen to the air entrainment device should be a nipple conforming to prEN 13544-2.

5.2 Air inlet attachments

Any air inlet attachment provided with or recommended for use with the air entrainment device shall neither affect the safety nor the performance of the device nor cover any marking of the device.

The attachment shall not become detached when tested as described in A.2.8 (normative).

6 Delivered oxygen concentration

When tested as described in annex A, the delivered oxygen concentration shall be as given in Table 1.

Table 1 - Delivered oxygen concentration

Designated O_2 concentration (%)	Delivered O_2 concentration	
	min. (%) $^{v}/_{v}$	max. (%) $^{v}/_{v}$
24	23	25
28	27	29
31	30	32
35	33	37
40	38	42
50	47	53
60	56	64

Additional information is given in annex B.

7 Marking and identification

EN 980 and EN 1041 apply with the following additions :

7.1 Marking

7.1.1 Each fixed concentration air entrainment device shall be marked with :

a) the designated oxygen concentration in characters at least 2,5 mm high ;

b) the recommended flow in l/min in characters at least 2,5 mm high.

7.1.2 The immediate packaging of the device shall also carry the above information, together with the following :

a) the name or trade mark of the manufacturer ;

b) a lot or serial number or date of manufacture ;

c) if designed for single use only, the words “SINGLE USE” or the appropriate symbol.

7.1.3 Air entrainment devices with a control to adjust the oxygen concentration shall conform to item b) of 7.1.1 and items a) to c) of 7.1.2 and in addition with either of the following :

a) The minimum and maximum settings shall be marked with their respective oxygen concentrations (see 8 d)) in characters at least 2,5 mm high, and the direction of movement of the control to increase the delivered oxygen concentration shall be indicated.

b) A scale of delivered oxygen concentration shall be provided, marking each of these designated concentrations listed in Table 1 which is attainable by the adjustment of the control.

7.2 Colour coding

7.2.1 If colour coding is used as an additional means of identification of the designated oxygen concentration on air entrainment devices, the colour code given in Table 2 shall be used. The colour codes shall be applied directly to the air entrainment device and shall have an area of at least 1 cm^2.

The colour coding shall either be visible through the immediate external packaging or shall be repeated on the outside of the immediate external packaging.

Table 2 - Colour coding

Designated O_2 concentration $\%\ {}^{v}/_{v}$	**Colour** **(see annex C for references of colours given as examples)**
24	Blue
28	White
31	Orange
35	Yellow
40	Red
50	Pink
60	Green

7.2.2 The colours of the code shall not be used for any purpose other than identifying the delivered oxygen concentration.

NOTE Air entrainment devices provided with a control to adjust the delivered oxygen concentration may use the colour code given in Table 2 to identify the selected values.

8 Information supplied by the manufacturer

With each package of devices, the manufacturer shall provide operating instructions and information complying with EN 1041 including :

a) a table or graph showing the relationship between the oxygen supply flow and the resulting total flow of the delivered air/oxygen mixture ;

b) the minimum, recommended and maximum flows of oxygen which enable the device to achieve the designed performance ;

c) if the device is intended for re-use, details of suitable methods of cleaning, disinfecting and/or sterilization ;

d) for devices in accordance with 7.1.3, a warning that means of determining the patient oxygenation should be used (e.g. pulse oximeter, oxygen monitor).

Annex A
(normative)

Method of test for delivered oxygen concentration

A.1 Apparatus

A.1.1 *Oxygen supply and flowmeter with control valve*, the flowmeter to be capable of delivering and measuring flows between 3 l/min and 30 l/min with an accuracy of ± 2,5 %.

A.1.2 *Sampling T-piece*, shown in Figure A.1.

NOTE 1 It is essential that the manufacturer designs the T-piece inlet to connect to the particular design of air entrainment device, and makes details of this T-piece available to test houses.

The side branch can be varied to suit the design of oxygen analyser, and it is essential that it provides a close fit to the oxygen sensor or analyser sampling tube in order to prevent leakage to or from the exterior.

NOTE 2 The inclusion of corrugated breathing tubing between the outlet of an air entrainment device and the face mask has been found to modify the inspired oxygen concentration. If an air entrainment device is intended to be used only with a particular delivery system, the manufacturer can perform these tests with the system attached, and shall record this fact in the test report(s).

A.1.3 *Oxygen analyser*, capable of measuring the concentration of oxygen with an accuracy of ± 0,1 % oxygen within the zone shown in Figure A.1.

A.1.4 Equipment capable of measuring barometric pressure, relative humidity and ambient temperature with an accuracy of ± 2 %.

A.2 Procedure

NOTE Good ventilation or scavenging of the mixture from the devices under test is necessary to prevent entrainment of air which has already been enriched by oxygen from previous experiments.

A.2.1 If the device is intended to be re-used, condition it prior to these tests by subjecting it to twenty cycles of cleaning and sterilization in accordance with manufacturer's instructions.

A.2.2 Carry out the tests at conditions of (22 ± 2) °C, 101,3 kPa and (50 ± 5) % RH, or correct results to these conditions.

A.2.3 Assemble the device to be tested to the T-piece (A.1.2) ensuring that there are no visible gaps which might permit leakage of air or gas. Connect the oxygen supply flowmeter (A.1.1) to the oxygen nipple with the tubing recommended by the manufacturer (see Figure A.2).

A.2.4 Calibrate the oxygen analyser (A.1.3) according to the manufacturer's instructions and connect or position it so as to take samples from the zone shown in Figure A.1.

A.2.5 Adjust the oxygen supply flowmeter control to the minimum flow stated by the manufacturer of the air entrainment device, and record the oxygen analyser reading after approximately 3 min. Correct the reading to 20 °C and 101,3 kPa (A.1.4).

A.2.6 Repeat the test at the recommended flow and at the maximum flow stated by the manufacturer of the air entrainment device.

A.2.7 If the device is intended for use with an air inlet attachment, repeat the tests with the attachment fitted.

A.2.8 Test the security of the air inlet attachment by securing the attachment so that it is not distorted and applying an axial tensile force of (5 ± 0,5) N to the oxygen nipple of the air entrainment device for (60 ± 2) s. Record whether the device separates from the air inlet attachment.

Repeat the test applying the axial force in the opposite direction, i.e. compressing the device into the attachment.