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Respiratory therapy equipment - Part 3: Air entrainment devices

Atemtherapiegeräte - Teil 3: Luftbeimischgeräte

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

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Respiratory therapy equipment - Part 3: Air entrainment devices

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

Atemtherapiegeräte - Teil 3: Luftbeimischgeräte

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Foreword

This document (EN 13544-3:2001+A1:2009) 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of an identical text or by endorsement, at the latest by March 2010, and conflicting national standards shall be withdrawn at the latest by March 2010.

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

This document includes Amendment 1, approved by CEN on 2009-07-30.

This document supersedes EN 13544-3:2001.

The start and finish of text introduced or altered by amendment is indicated in the text by tags ▌A1⟩ ⟨A1▐.

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, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and 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) [A1] the name or trade mark of the manufacturer and the name and address of the authorized representative where the manufacturer does not have a registered place of business in the European Community; [A1]

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

c) [A1] if designed for single use only, the words “SINGLE USE” or the appropriate symbol. For single use devices the manufacturer shall disclose the risks associated with reusing in the instructions for use or upon request.

NOTE The manufacturer's attention is drawn to the regulatory provision for a consistent use of indication for single use devices. [A1]

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) [A1] 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). The instructions for use shall contain the date of issue or the latest revision. [A1]

[A1]

e) If phthalates are incorporated in parts of the medical devices coming directly or indirectly into contact with the patient the medical device shall be labelled accordingly. If such devices are used for the treatment of children or treatment of pregnant or nursing women, the residual risk has to be identified and stated in the instructions for use.

NOTE Attention is drawn to substances which are carcinogenic, mutagenic or toxic to reproduction. A1

9 A1 Usability

The manufacturer shall address in a usability engineering process the risk resulting from poor usability (see EN 60601-1-6 and EN 62366).

Check compliance by inspection of the usability engineering file.

10 Clinical evaluation

A clinical evaluation shall be performed and documented in the risk management file.

Check compliance by inspection of the risk management file. A1