Respiratoorse teraapia seadmed. Osa 3: Õhuärakande seadmed KONSOLIDEERITUD TEKST

Respiratory therapy equipment - Part 3: Air entrainment devices CONSOLIDATED TEXT

EESTI STANDARDIKESKUS
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NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 13544-3:2002+A1:2009 sisaldab Euroopa standardi EN 13544-3:2001+A1:2009 ingliskeelset teksti.	This Estonian standard EVS-EN 13544-3:2002+A1:2009 consists of the English text of the European standard EN 13544-3:2001+A1:2009.
Standard on kinnitatud Eesti Standardikeskuse 30.10.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 30.10.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 09.09.2009.	Date of Availability of the European standard text 09.09.2009.
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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

This European Standard was approved by CEN on 7 April 2001 and includes Amendment 1 approved by CEN on 30 July 2009.

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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of an identical text or by endorsement, at the latest by March 2010, and conflicting national standards shall be withdrawn at the latest by March 2010.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.