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Lungventilatorer –
Del 4: Särskilda krav på manuella återupplivningsballonger (ISO 10651-4:2002)

Lung ventilators –
Part 4: Particular requirements for operator-powered resuscitators (ISO 10651-4:2002)

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Europastandarden EN ISO 10651-4:2009 gäller som svensk standard. Detta dokument innehåller den officiella engelska versionen av EN ISO 10651-4:2009.

Denna standard ersätter SS-EN ISO 10651-4, utgåva 1 och SS-EN ISO 10651-4/AC:2006, utgåva 1.

The European Standard EN ISO 10651-4:2009 has the status of a Swedish Standard. This document contains the official English version of EN ISO 10651-4:2009.

This standard supersedes the Swedish Standard SS-EN ISO 10651-4, edition 1 and SS-EN ISO 10651-4/AC:2006, edition 1.

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 10651-4

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Supersedes EN ISO 10651-4:2002

English Version

Lung ventilators - Part 4: Particular requirements for operator-powered resuscitators (ISO 10651-4:2002)

Ventilateurs pulmonaires - Partie 4: Exigences relatives aux ressuscitateurs à puissance motrice manuelle (ISO 10651-4:2002)

Lungenbeatmungsgeräte - Teil 4: Anforderungen an anwenderbetriebene Wiederbelebungsgeräte (Handbeatmungsgeräte) (ISO 10651-4:2002)

This European Standard was approved by CEN on 21 March 2009.

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN ISO 10651-4:2009: E

Contents

Foreword

The text of ISO 10651-4:2002 has been prepared by Technical Committee ISO/TC 121 “Anaesthetic and respiratory equipment” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 10651-4:2009 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of an identical text or by endorsement, at the latest by October 2009, and conflicting national standards shall be withdrawn at the latest by March 2010.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 supersedes EN ISO 10651-4:2002.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EC Directive.

For relationship with EC Directive, see informative Annex ZA, which is an integral part of this document.

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Endorsement notice

The text of ISO 10651-4:2002 has been approved by CEN as a EN ISO 10651-4:2009 without any modification.

1 Scope

This European Standard specifies requirements for operator-powered resuscitators intended for use with all age groups and which are portable and intended to provide lung ventilation to individuals whose breathing is inadequate. Operator-powered resuscitators for infants and children are designated according to body mass range and approximate age equivalent.

Electrically- and gas-powered resuscitators are not covered by this European Standard.

NOTE Annex B contains rationale statements for this Part of this European Standard. The clauses and subclauses which have corresponding rationale statements are marked with ***R*)** after their number.

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 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 148-1, *Respiratory protective devices - Threads for facepieces –Part 1: Standard thread connection.*

EN 556: 1994+A1:1998, *Sterilization of medical devices - Requirements for terminally-sterilized medical devices to be labelled "STERILE*".

EN 737-1, *Medical gas pipeline systems - Part 1: Terminal units for compressed medical gases and vacuum*.

EN 868-1, *Packaging materials and systems for medical devices which are to be sterilized - Part 1: General requirements and test methods* .

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

EN 1281-1, *Anaesthetic and respiratory equipment - Conical connectors - Part 1: Cones and sockets*.

prEN 13544-2:2000, *Respiratory therapy equipment – Part 2 : Specifications for tubing and connectors*.

EN ISO 4135:1996, *Anaesthesiology – Vocabulary (ISO 4135 :1995)*.

3 Terms and definitions

For the purposes of this part of EN ISO 10651, the terms and definitions given in EN ISO 4135:1996 and the following terms and definitions apply.

NOTE Some of the definitions have been taken from EN ISO 4135, but they are included in this European Standard for convenience; other definitions, which are given in EN ISO 4135, for apparatus in general, have been modified slightly for the purposes of this European Standard as they apply specifically to resuscitators.

3.1
reverse leakage
volume of expired gas which does not pass through the expiratory port but returns to the resuscitator

3.2
bag inlet valve
valve activated by the subatmospheric pressure in the compressible unit of the resuscitator to refill the compressible unit with gas at ambient pressure

3.3
bag refill valve
valve, with no manual trigger, activated by the sub-atmospheric pressure in the compressible unit of the resuscitator to refill the compressible unit from a pressurized gas source

3.4
compressible unit
that part of an operator-powered resuscitator e.g. a bag or bellows that, when compressed by the operator, delivers a volume of gas

3.5
delivered oxygen concentration
average concentration of oxygen in the gas delivered from the resuscitator

3.6
delivered volume, V_{del}
volume of gas, expressed in millilitres, leaving the resuscitator through the patient connection port during the inspiratory phase

3.7
forward leakage
volume of gas produced by the resuscitator during the inspiratory phase which does not pass through the patient port to the patient but passes to the atmosphere

3.8
minute volume, $\dot{V}$
volume of gas per minute entering or leaving the patient's lungs

3.9
operator-powered resuscitator
resuscitation device in which ventilation of the lungs is produced by the operator compressing the compressible unit of the device

NOTE Hereinafter called "resuscitator".

3.10
patient connection port
that opening through which gas flows to and from the patient

3.11
patient connection port connector
connector at the patient connection port which connects directly to a face mask or an appropriate mating airway device

3.12
patient valve
valve in the breathing system that directs gas into the lungs for the inspiratory phase and into the atmosphere during the expiratory phase

3.13
pressure limiting system
means for limiting the maximum delivery pressure

3.14
resuscitator deadspace, $V_{D,app}$
that volume of previously exhaled gas which is delivered from the resuscitator in the succeeding inspiratory phase

3.15
tidal volume, V_T
volume of gas, expressed in millilitres, entering or leaving the patient or the lung model during the inspiratory or expiratory phase

3.16
ventilatory cycle
ventilation cycle comprising the inspiratory phase plus the expiratory phase of breathing

4 Connectors

4.1 Patient connection port connector

The patient connection port connector of the resuscitator shall be a 15 mm female and 22 mm male coaxial connector complying with EN 1281-1.

4.2 *R*) Expiratory port connector for breathing gases

If an expiratory port connector is provided, it shall be one of the following :

a) a 30 mm male conical connector complying with EN 1281-1 or ;

b) a permanent connection or propriatory connector incompatible with EN 1281-1 and EN 737-1 ;

and with a means to prevent connection with internal lumen to any breathing attachment.

4.3 Face mask connectors

If provided with the resuscitator, face masks shall have either a 22 mm female connector or a 15 mm male connector which shall mate with the corresponding connectors specified in EN 1281-1.

4.4 *R*) Bag refill valve connectors

If a conical connector is provided for attachment of a bag refill valve, it shall be a unique 32 mm female design. The dimensions of this connector, when submitted to the test gauge given in Figure A.1, shall fit within the tolerance steps.

4.5 Bag inlet valve connectors

Bag inlet valve connectors shall not be compatible with connectors dimensioned in accordance with EN 1281-1. The bag inlet valve should be designed to minimize the risk of unintentional connection of breathing attachments which might block the valve

4.6 Threaded gas filter connectors

If the resuscitator is fitted with a threaded gas filter connection, it shall comply with EN 148-1.

4.7 Oxygen tube connector and pressure gauge connector

The oxygen tube connector, if provided, shall comply with prEN 13544-2:2000. The pressure gauge connector (if provided) shall not be compatible with tubing fitting the oxygen tube connector.

5 Operational requirements

5.1 General

All test performance requirements in this European Standard shall be satisfied when the resuscitator is operated by one person.

5.2 *R*) Dismantling and reassembly

A resuscitator intended to be dismantled by the user, e.g. for cleaning, etc. should be designed so as to minimize the risk of incorrect reassembly when all parts are mated.

The manufacturer shall recommend a functional test of operation to be carried out after reassembly (see 10.2d)).