

GSO ISO 10651-4:2015

ISO 10651-4:2002

مواصفة قياسية خليجية

أجهزة التنفس الصناعي -- الجزء 4: المتطلبات الخاصة
أجهزة التنفس الصناعي المشغلة بالقدرة

Gulf Standard

Lung ventilators -- Part 4: Particular requirements
for operator-powered resuscitators

ICS: 11.040.10

اللغة الإنجليزية – English Language

الطبعة 1 – 21/12/2015 – Edition 1



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قرر المجلس الفني لهيئة التقييس لدول مجلس التعاون لدول الخليج العربية في الاجتماع رقم (37) الذي عقد بتاريخ 1437/09/03 هـ ، الموافق 2015/12/21 م اعتماد المواصفة القياسية الخليجية رقم GSO ISO 10651-4:2015 وعنوانها "أجهزة التنفس الصناعي -- الجزء 4: المتطلبات الخاصة أجهزة التنفس الصناعي المشغلة بالقدرة " باللغة الانجليزية التي تم دراستها وتبنيها بالمصادقة عبر المسار السريع عن المنظمة الدولية للتقييس رقم ISO 10651-4:2002 .

Gulf Foreword

GCC Standardization Organization (GSO) is a regional organization which consists of the national standardization bodies of GCC member states. One of GSO main functions is to issue gulf standards and technical regulations through specialized technical committees.

GSO Technical Council in its meeting number (37) held on 03/09/1437 H , which corresponds to 21/12/2015 has approved gulf standard No GSO ISO 10651-4:2015 titled "Lung ventilators -- Part 4: Particular requirements for operator-powered resuscitators" in English language which was studied and adopted by endorsement from International Organization for Standardization Standard ISO 10651-4:2002 through fast track .

Lung ventilators —

Part 4:

Particular requirements for operator-powered resuscitators

Ventilateurs pulmonaires —

*Part 4: Exigences relatives aux ressuscitateurs à puissance motrice
manuelle*





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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 3.

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 part of ISO 10651 may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 10651-4 was prepared by the European Committee for Standardization (CEN) in collaboration with Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Throughout the text of this document, read "...this European Standard..." to mean "...this International Standard...". ISO 10651 consists of the following parts, under the general title *Lung ventilators*:

- *Part 1: Requirements*
- *Part 2: Particular requirements for home care ventilators*
- *Part 3: Particular requirements for emergency and transport ventilators*
- *Part 4: Particular requirements for operator-powered resuscitators*

Annex A forms a normative part of this part of ISO 10651. Annex B is for information only.

For the purposes of this part of ISO 10651, the CEN annex regarding fulfilment of European Council Directives has been removed.

Foreword

This document (EN ISO 10651-4:2002) has been prepared by Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI, in collaboration with Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment".

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 September 2002, and conflicting national standards shall be withdrawn at the latest by September 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 EU Directive(s).

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

Annex B is 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, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Lung ventilators —

Part 4:

Particular requirements for operator-powered resuscitators

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 1 to entry: 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

Bibliography

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

