INTERNATIONAL STANDARD

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Lung ventilators for medical use — Particular requirements for basic safety and essential performance —

Part 5: Gas-powered emergency resuscitators

Ventilateurs pulmonaires à usage médical — Exigences particulières pour la sécurité de base et les performances essentielles —

Partie 5: Appareils de réanimation d'urgence alimentés par gaz

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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 2.

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

ISO 10651-5 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 3, *Lung ventilators and related equipment*.

This first edition of ISO 10651-5, together with ISO 10651-4:2002, cancels and replaces ISO 8382:1988, which has been technically revised.

ISO 10651 consists of the following parts, under the general title *Lung ventilators for medical use — Particular requirements for basic safety and essential performance*:

— *Part 2: Home care ventilators for ventilator-dependent patients*

— *Part 3: Particular requirements for emergency and transport ventilators*

— *Part 4: Particular requirements for operator-powered resuscitators*

— *Part 5: Gas-powered emergency resuscitators*

— *Part 6: Home-care ventilatory support devices*

NOTE ISO 10651-1:1993, *Lung ventilators for medical use — Part 1: Requirements*, was withdrawn in 2001 and has been revised as IEC 60601-2-12:2001, *Medical electrical equipment — Part 2-12: Particular requirements for the safety of lung ventilators — Critical care ventilators*.

Introduction

For victims whose lives are at risk from respiratory failure, in particular during cardiac arrest, resuscitation councils and associations teach that the best ultimate outcome will be achieved if there is a continuous chain of care starting with earliest possible bystander **cardiopulmonary resuscitation** and continuing until the victim can be put under professional medical care. In order to improve the care possible at the early stages of this chain, authorities and organizations are training non-specialized personnel in key situations, such as where people congregate or where there are increased risks, so that they can be available to provide a higher level of care with a minimum of delay.

There is a growing realization that the effectiveness of such intervention can be greatly enhanced by the use of certain basic **equipment**, such as that which provides ventilation whilst avoiding mouth-to-mouth contact. Simple, **gas-powered emergency resuscitators** can deliver controlled ventilation for this purpose and this document specifies the criteria they are required to satisfy.

In this part of ISO 10651, the following symbols and notations are used:

— requirements, compliance with which can be tested, and definitions: roman type;

— notes, explanations, advice, introductions, general statements and references: smaller roman type;

— test specifications: *italic type*;

— terms defined in ISO 4135:2001, IEC 60601-1:1988 or in this part of ISO 10651: **bold type**.

Throughout this part of ISO 10651, text for which a rationale is provided in Annex A is indicated by an asterisk (*).

Lung ventilators for medical use — Particular requirements for basic safety and essential performance —

Part 5: Gas-powered emergency resuscitators

1 * Scope

This part of ISO 10651 specifies the basic safety and essential performance requirements for **gas-powered emergency resuscitators** (3.10) intended for use with humans by **first responders**. This **equipment** is intended for emergency field use and is intended to be continuously **operator** attended in **normal use**.

This part of ISO 10651 also specifies the requirements for **resuscitator sets** (3.22).

This part of ISO 10651 is not applicable to electrically-powered **resuscitators**.

NOTE ISO 10651-3 covers emergency and transport ventilators.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 31 (all parts), *Quantities and units*

ISO 32, *Gas cylinders for medical use — Marking for identification of content*

ISO 1000, *SI units and recommendations for the use of their multiples and of certain other units*

ISO 4135:2001, *Anaesthetic and respiratory equipment — Vocabulary*

ISO 5356-1, *Anaesthetic and respiratory equipment — Conical connectors — Part 1: Cones and sockets*

ISO 5356-2, *Anaesthetic and respiratory equipment — Conical connectors — Part 2: Screw-threaded weight-bearing connectors*

ISO 5359, *Low-pressure hose assemblies for use with medical gases*

ISO 5367, *Breathing tubes intended for use with anaesthetic apparatus and ventilators*

ISO 9170-1, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

ISO 10297, *Gas cylinders — Refillable gas cylinder valves — Specification and type testing*

ISO 10524-1, *Pressure regulators for use with medical gases — Part 1: Pressure regulators and pressure regulators with flow-metering devices*

ISO 10524-3, *Pressure regulators for use with medical gases — Part 3: Pressure regulators integrated with cylinder valves*

ISO 11607, *Packaging for terminally sterilized medical devices*

ISO 14971, *Medical devices — Application of risk management to medical devices* and Amendment 1:2003

ISO 15223:2000, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied* and Amendment 1:2002 and Amendment 2:2004

ISO 17664, *Sterilization of medical devices — Information to be provided by the manufacturer for the processing of resterilizable medical devices*

ISO 23328-1:2003, *Breathing system filters for anaesthetic and respiratory use — Part 1: Salt test method to assess filtration performance*

ISO 23328-2:2002, *Breathing system filters for anaesthetic and respiratory use — Part 2: Non-filtration aspects*

IEC 60529:2001, *Degrees of protection provided by enclosures (IP code)*

IEC 60601-1:1988, *Medical electrical equipment — Part 1: General requirements for safety* and Amendment 1:1991 and Amendment 2:1995

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 4135:2001, IEC 60601-1:1988 and the following apply. For convenience, the sources of all defined terms used in this document are given in Annex E.

3.1
accompanying documents
documents accompanying **resuscitator** or **resuscitator sets** and containing all important information for the **user**, **operator**, installer or assembler of the **resuscitator**, particularly regarding safety

NOTE Adapted from IEC 60601-1:1988, definition 2.1.4.

3.2
automatic pressure-cycled resuscitator
resuscitator in which the cycling from the **inspiratory phase** to the **expiratory phase** occurs after attaining a pressure determined by the control setting

3.3
automatic time-cycled resuscitator
resuscitator in which the cycling between the **inspiratory phase** and **expiratory phase** is controlled automatically at time intervals determined by the control setting

3.4
automatic volume-cycled resuscitator
resuscitator in which the cycling from the **inspiratory phase** to the **expiratory phase** occurs after the delivery of a **delivered volume** determined by the control setting

3.5
cardiopulmonary resuscitation
combination of rescue breathing and chest compressions delivered to victims thought to be in cardiac arrest

[*AHA Guidelines for Cardiopulmonary Resuscitation and Emergency Care*]

3.6
clearly legible
capable of being read by the **operator** or other relevant person with normal vision

NOTE See also 8.2.1.

3.7
*** delivered volume**
V_{del}
volume of gas delivered through the **patient connection port** during an **inspiratory phase**

3.8
demand valve
part of the **resuscitator** that delivers a flow of gas related to a reduction of pressure generated by the **patient** at the **patient connection port**

3.9
first responder
individual who has been trained to provide primary response to a respiratory emergency

EXAMPLE 1 Fire fighter.

EXAMPLE 2 Emergency medical technician.

3.10
gas-powered emergency resuscitator
resuscitator
portable **equipment**, powered by compressed gas, intended for immediate use to provide lung ventilation in the resuscitation of individuals who have sudden breathing difficulties

3.11
inadvertent positive end-expiratory pressure
inadvertent PEEP
unintended positive pressure at the **patient connection port** at the end of the **expiratory phase**

3.12
intermediate hose
hose that conducts gas between parts of the **resuscitator**

3.13
manually-cycled resuscitator
resuscitator in which the **inspiratory phase** and **expiratory phase** are controlled by a repeated manual action of the **operator**

NOTE A **demand valve** that can be overridden with a manual trigger is, for the purposes of this document, classified as a 'manually-cycled resuscitator incorporating a demand valve' and not as a 'demand valve' as they are commonly termed in some countries.

3.14
minute volume
$\dot{V}$
volume of gas per minute entering or leaving the **patient's** lungs

3.15
operator
person handling the **resuscitator**

NOTE Adapted from IEC 60601-1:1988, definition 2.12.17.

3.16
patient-triggered resuscitator
resuscitator in which the cycling from the **expiratory phase** to the **inspiratory phase** is triggered by an inspiratory effort of the **patient**

3.17
patient-triggering
mode of operation in which a reduction of pressure generated by the **patient** at the **patient connection port** initiates the set **inspiratory phase**

3.18
patient valve
valve in the **resuscitator breathing system** that directs gas into the lungs during the **inspiratory phase** and from the lungs into the atmosphere during the **expiratory phase**

3.19
pressure-limiting device
means for limiting the maximum pressure within the **resuscitator breathing system**

3.20
resuscitator breathing system
breathing system bounded by the **low-pressure gas input port(s)**, the gas intake port(s) and the **patient connection port**, together with the **fresh gas intake port** and **exhaust port(s)**, if these are provided

3.21
resuscitator dead space
volume of previously exhaled gas within the **resuscitator breathing system** that is delivered to the **patient** in the succeeding **inspiratory phase**

3.22
resuscitator set
pack of all the necessary components that enable the **resuscitator** to be carried to the site of a resuscitation emergency and that enable the **resuscitator** to be made ready for immediate use

3.23
safety hazard
potentially detrimental effect on the **patient**, other persons, animals, or the surroundings, arising directly from the **resuscitator**

NOTE Adapted from IEC 60601-1:1988, definition 2.12.18.

3.24
single fault condition
condition in which a single means for protection against a **safety hazard** in the **resuscitator** is defective or a single external abnormal condition is present

NOTE Adapted from IEC 60601-1:1988, definition 2.10.11.

4 General requirements

4.1 General

The **resuscitator** shall, when transported, stored, installed, operated in **normal use**, and maintained according to the **accompanying documents**, cause no **safety hazard** that could reasonably be foreseen and that is not connected with its intended application, in **normal condition** and in **single fault condition**.

A **risk management process** complying with ISO 14971 shall be performed.

In applying ISO 14971:

a) the term “medical device” shall assume the same meaning as **resuscitator**;

b) the term “fault conditions” referred to in ISO 14971 shall include, but shall not be limited to, **single fault conditions** identified in this part of ISO 10651;

c) where this part of ISO 10651 specifies measurable requirements addressing particular **risks**, and these requirements are complied with, the **residual risks** of these requirements shall be presumed to be acceptable unless there is **objective evidence** to the contrary.

This part of ISO 10651 specifies requirements that are generally applicable to **risks** associated with **resuscitators**, and is intended to serve as a tool during the **risk management process**. The **risk management process** identifies not only those **safety hazards** addressed by this part of ISO 10651, but also all **safety hazards**, their associated **risks** and **risk control** measures.

Conditions or faults that can give rise to **safety hazards** are identified in the clauses of this part of ISO 10651. In these cases, it will often be necessary to carry out a **risk management process** to determine what the actual **safety hazards** are and the tests that need to be done to show that the identified **safety hazards** do not arise in the specified circumstance.

It is recognized that the manufacturer might not be able to follow all the processes identified in this part of ISO 10651 for each constituent component of the **resuscitator**, such as proprietary components, subsystems of non-medical origin, and legacy parts. In this case, the manufacturer should take special account of the need for additional **risk control** measures.

Where requirements of this part of ISO 10651 refer to freedom from unacceptable **risk**, the manufacturer, in accordance with the manufacturer’s policy for determining acceptable **risk,** determines the acceptability or unacceptability of this **risk**.

*Check compliance by inspection of the **risk management file**. The requirements of this clause and all requirements of this part of ISO 10651 referring to inspection of the **risk management file** are considered to be satisfied if the manufacturer has*

— established a risk management process,

— established acceptable levels of risk, and

— demonstrated that the residual risk is acceptable (in accordance with the policy for determining acceptable risk).

4.2 Other test methods

The manufacturer may use type tests different from those detailed within this part of ISO 10651 if an equivalent degree of safety is obtained. However, in the event of dispute, the methods specified herein shall be used as the reference methods.

4.3 Acceptance criteria

Many of the test clauses within this part of ISO 10651 establish acceptance criteria for performance aspects. These acceptance criteria shall always be met.

When the manufacturer chooses to specify in the **accompanying documents** higher performance levels than those specified within this part of ISO 10651, these manufacturer-specified levels become the acceptance levels and shall also be met.

5 Constructional requirements

5.1 General

5.1.1 Materials of construction

All gas conducting parts shall be constructed from materials selected to take into account the chemical and physical properties of any substances that the **accompanying documents** indicate:

— can be administered through the **resuscitator**, and

— can be used to clean and disinfect or sterilize the **resuscitator**.

*Check compliance by inspection of the **risk management file**.*

5.1.2 Surfaces, corners and edges

Rough surfaces, sharp corners, open ends of tubular components and edges that can cause injury or damage shall be avoided or covered. Particular attention shall be paid to the removal of burrs.

Check compliance by inspection.

5.1.3 Leaching of substances

The **resuscitator** and parts thereof shall be designed and manufactured to minimize health risks due to substances leached from the **resuscitator** or its components during use. Particular attention shall be paid to the toxicity of materials and their compatibility with substances and gases with which they enter into contact during **normal use**.

*Check compliance by inspection of the **risk management file**.*

5.1.4 Breathing tubes

Breathing tubes with an internal diameter of more than 18 mm, intended for use in the **resuscitator breathing system**, shall comply with ISO 5367.

Check compliance by application of the requirements of ISO 5367.

5.1.5 Supply of sterile components

If a claim is made in the labelling that a product is sterile, it shall have been sterilized using an appropriate, validated method, as described in ISO 11134, ISO 11135, ISO 11137, ISO 11138, or ISO 14937.

The packaging for **resuscitators** or parts supplied sterile shall meet the requirements of ISO 11607. Such packaging shall not be capable of re-closure without clearly revealing that it has been opened.

Non-sterile packaging systems shall be designed to maintain products that are intended to be sterilized before use at their intended level of cleanliness and shall be designed to minimize the risk of microbial contamination.

*Check compliance by a review of the **accompanying documents** for methods of sterilization and disinfection and by inspection of the relevant validation reports.*

5.1.6 * Breathing system filter

Any **breathing system filter**, either incorporated into the **resuscitator** or indicated in the **accompanying documents** for use with the **resuscitator**, shall comply with the applicable parts of ISO 23328-1 and ISO 23328-2.

Check compliance by application of the requirements of ISO 23328-1 and ISO 23328-2.

5.1.7 Arrangement of functions

Any **single fault condition** shall not cause any monitoring or alarm system function, as specified in this part of ISO 10651, and the corresponding ventilation control function to fail in such a way that the monitoring or alarm system function becomes simultaneously ineffective, and thus fails to detect the loss of the monitored **resuscitator** function.

*Check compliance by simulation of a **single fault condition** and visual inspection.*

5.1.8 Protection against accidental adjustments

Means of protection against accidental alteration of control settings, including the “on-off” switch, shall be provided. Mechanical techniques such as locks, shielding, friction-loading and detents may be used.

Check compliance by visual inspection following the instructions for use.

5.1.9 Selector switches/controls

For controls that are not continuously variable, means shall be provided that prevent the selector from remaining in an intermediate position.

EXAMPLE 1 An “on-off” switch.

EXAMPLE 2 An oxygen concentration selector.

EXAMPLE 3 A selector for preset, discrete values of **delivered volume** or frequency.

Check compliance by inspection.

5.1.10 Accuracy of operating data

While the **resuscitator** is in **normal use**, it shall deliver ventilation accuracy as indicated in the instructions for use. See also 8.3.2.2.

Verify compliance, by means of the appropriate test methods described in this part of ISO 10651.

5.1.11 * Resuscitator set

The **resuscitator** shall be supplied with or the **accompanying documents** shall recommend a **resuscitator set,** including a medical gas supply system that complies with the relevant requirements of this part of ISO 10651.

Check compliance by inspection.

5.2 Connectors

5.2.1 Connection to the medical gas supply system

If a detachable hose assembly is provided for connection between the **resuscitator** and the medical gas supply system, it shall comply with ISO 5359. If a hose assembly is permanently connected to the **resuscitator**, the connection to the medical gas supply system shall be by means of:

— either a probe complying with ISO 9170-1, or

— a permanent connector.

NOTE A permanent connector is one that can be separated only by use of a tool.

Check compliance by inspection.

5.2.2 Connection to the high-pressure gas input port

The connection of the hose to the **high-pressure gas input port** of the **resuscitator** shall be by means of:

— a non-interchangeable, screw-threaded connector complying with ISO 5359,

— a probe complying with ISO 9170-1, or

— a permanent connector.

Check compliance by inspection.

5.2.3 Patient connection port connector

The **patient connection port** connector of the **resuscitator** shall be a coaxial 15 mm / 22 mm connector complying with ISO 5356-1.

Check compliance by application of the requirements of ISO 5356-1.

5.2.4 Facemask connector

Facemasks shall have either a 22 mm female connector or a 15 mm male connector that shall mate with the corresponding connectors specified in ISO 5356-1.

Check compliance by application of the requirements of ISO 5356-1.

5.2.5 * Gas exhaust port connector

If a gas **exhaust port** connector is provided, it shall be:

— a 30 mm male conical connector complying with ISO 5356-1; or

— a proprietary connector incompatible with ISO 5356-1 and ISO 9170-1 having a means to prevent the connection of any breathing attachment conforming to ISO 5356-1 or ISO 5356-2 to the internal lumen.

Check compliance by inspection and by application of the requirements of ISO 5356-1 or ISO 5356-2 and ISO 9170-1.

5.2.6 Resuscitator inspiratory limb connectors

Connectors in the inspiratory limb of the **resuscitator**, if conical, shall comply with ISO 5356-1 and ISO 5356-2.

Non-conical connectors shall not engage with conical connectors complying with ISO 5356-1 or ISO 5356-2 unless they comply with the engagement, disengagement and leakage requirements of ISO 5356-1 or ISO 5356-2.

Check compliance by inspection.

5.2.7 Emergency air intake port

An emergency air intake port shall:

— be provided,

— comply with the requirements of 7.1.2.2 and 7.1.2.3, and

— not accept any connector complying with ISO 5356-1 or ISO 5356-2.

Check compliance by inspection.

6 Operational requirements

6.1 General

6.1.1 * Patient valve function after contamination with vomitus

When the **resuscitator** is tested in accordance with the test described in B.3.1, the time for cleaning and restoration to normal function shall not exceed 20 s. It shall then meet the requirements specified in Clause 7. The valve housing should be constructed so that operation of the mechanism can be observed by the **operator**, e.g. through a transparent housing.

NOTE Observation of the functioning mechanism of the **patient valve** can assist the **operator** in detecting abnormal operation.

Check compliance by the methods described to B.3.1 and Clause 7.

6.1.2 Cleaning, and sterilization or disinfection

All parts and **accessories** indicated for reuse in the **accompanying documents**, which can be contaminated by exhaled **patient** gas during **normal use** and during the **single fault condition** simulated in B.3.10, shall be capable of being cleaned, and sterilized or disinfected.

Parts and **accessories** labelled as capable of being sterilized shall be accompanied with information according to ISO 17664.

Check compliance by inspection.

6.1.3 * Functional test after reassembly

6.1.3.1 Reassembly

A **resuscitator** intended to be dismantled by the **operator** (e.g. for cleaning) shall be designed to minimize the risk of incorrect reassembly when using only items supplied with the **resuscitator set**.

Check compliance by inspection.

6.1.3.2 Functional test

The **accompanying documents** shall indicate a functional test procedure that can be carried out by the **operator** after reassembly, using only items supplied with the **resuscitator set,** which demonstrates that the **resuscitator** has been properly reassembled.

Check compliance by the method described in B.3.2.

6.1.4 Flow-direction-sensitive component connectors

Any **operator**-detachable, **flow-direction-sensitive component** shall be so designed that it cannot be fitted in such a way as to present a **safety hazard** to the **patient**.

Check compliance by inspection.