American National Standard

# ANSI/AAMI/ ISO 10651-5:2006

Lung ventilators for medical use—Particular requirements for basic safety and essential performance—Part 5: Gas-powered emergency resuscitators

AAMI
Advancing Safety in Medical Technology

**This document was approved and published when the U.S. TAG for TC 121 was held by ASTM, but it is now an AAMI standard. The original formatting has been maintained, so there are some variations from the typical AAMI style.**

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**ANSI/ISO 10651-5**

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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*

MOD in ANSI/ISO 10651-5 means that ASTM International has approved the standard as an American National Standard with deviations. The U.S. deviations are appended to the end of ANSI/ISO 10651-5.

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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*