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Breathing machines for medical use — Lung ventilators

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Foreword

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Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council. They are approved in accordance with ISO procedures requiring at least 75 % approval by the member bodies voting.

International Standard ISO 5369 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*.

Users should note that all International Standards undergo revision from time to time and that any reference made herein to any other International Standard implies its latest edition, unless otherwise stated.

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Breathing machines for medical use — Lung ventilators

0 Introduction

The main purpose in the preparation of this International Standard was to specify minimum requirements for the design and construction of lung ventilators for medical use. The aim was to ensure that machines designed for this purpose should be safe and be compatible with other apparatus used in similar applications throughout the world. Since lung ventilators have different capabilities, test procedures were developed to provide information concerning their behaviour when used to ventilate lungs with different characteristics.

Progress in this field has been rapid and is still continuing. For this reason no attempt has been made in section two to specify the characteristics of an ideal ventilator. It was considered that any such specification would soon be outdated and that it might also inhibit further developments in this field. However it is intended to include further developments dealing with safety and performance of lung ventilators. These developments may incorporate new functions and ventilatory patterns. In view of the known effects of lung ventilator characteristics on the patient's circulatory and respiratory function, it was considered important that the manufacturers should provide as much information as possible for the use of the prospective purchaser. To facilitate this exchange of information a test procedure has been devised utilizing an example of a test lung with a number of different, but standardized, impedances to lung ventilator output. It is intended that information derived from tests on this model should supplement other information customarily provided by the manufacturer.

Test methods are given in annex A and test data for constant-flow generators are given in annex B: both annexes form an integral part of this International Standard. Respiratory data for normal children are given, for information purposes, in annex C.

1 Scope and field of application

This International Standard specifies basic requirements for lung ventilators for medical use.

Section one defines the main classes of breathing machines used in medical practice and indicates how these may be further subdivided according to their mode of action.

Section two gives definitions of the terms used in the field of lung ventilators designed for adult, paediatric and neonatal patients. Characteristics for lung ventilators are also specified.

2 References

ISO 5356, *Anaesthetic and respiratory equipment — Conical connectors* —

Part 1 : Cones and sockets.

Part 2 : Screw-threaded weight-bearing connectors.

ISO 8185, *Humidifiers for medical use — Safety requirements.*

IEC Publication 601-1, *Safety of medical electrical equipment — Part 1 : General requirements.*

IEC Publication 601-2-12, *Medical electrical equipment — Part 2: Particular requirements for the safety of lung ventilators.*¹⁾

IEC Publication 601-2-13, *Medical electrical equipment — Part 2: Particular requirements for the safety of anaesthetic machines.*¹⁾

1) At present at the stage of draft.

Section one : Breathing machines — General

3 Classification and definitions of types of breathing machines

Class of equipment	Classification and definition
3.1 Lung ventilator	Automatic device which is connected to the patient's airway and is designed to augment or provide the patient's ventilation. The types of lung ventilators are as follows : 3.1.1 controller : Apparatus which inflates the patient's lungs independently of the patient's inspiratory effort. 3.1.2 assistor : Device designed to augment the patient's inspirations synchronously with his inspiratory effort. 3.1.3 assistor-controller : Apparatus which is designed to function either as an assistor or a controller and which may, in default of the patient's inspiratory effort, automatically function as a controller.
3.2 Resuscitator	Portable device used in emergency situations to provide lung ventilation to individuals whose breathing is inadequate. Resuscitators are classified according to their prime movers as follows : a) operator-powered; b) gas-powered; c) electrically powered.
3.3 Respiratory therapy ventilator	Device which is connected to the patient's airway and is primarily designed to deliver an aerosol and/or augment ventilation.
3.4 External body ventilator	Machine designed to augment or replace the patient's ventilation by means of the application of intermittent or alternating pressures to the trunk. External body ventilators are classified as follows : 3.4.1 tank or cabinet : External body ventilator in which the patient is enclosed to his neck in a rigid airtight chamber. 3.4.2 cuirass : External body ventilator in which all or part of the trunk is in an airtight enclosure, forming or incorporating a rigid frame. 3.4.3 belt : External body ventilator consisting of a flexible airtight bag wrapped around the patient's trunk. When inflated the bag produces forced expiration followed by inspiration upon deflation.
3.5 Rocking apparatus	Device used to produce or aid ventilation by using the weight of the abdominal contents to move the diaphragm.
3.6 Electrostimulator	Apparatus in which activity of the respiratory musculature is induced by electric impulses acting on the corresponding nerves or muscles.

Section two : Lung ventilators

4 Definitions related to the performance of lung ventilators

For the purposes of this International Standard, the following definitions apply.

4.1 (ventilatory) frequency, f : The number of breathing cycles per minute (bpm).

4.2 tidal volume, V_t : Volume of gas, expressed in millilitres, entering or leaving the patient (or the test lung) during the inspiratory or expiratory phase time. The physical conditions under which measurements are made should be given.

4.3 minute volume, $\dot{V}_E$: Volume of gas, expressed in litres in 1 min, entering or leaving the patient (or the test lung). The physical conditions under which measurements are made should be given.

4.4 volumetric displacement: That volume, expressed in millilitres, passed per cycle, during the inspiratory phase through the patient connection port when the pressures at the intake to the ventilator and at the outlet from the patient connection port are equal to the atmospheric pressure. (Such a volume may or may not be equal to the patient's tidal volume.)

4.5 breathing system: Those gas pathways continuously or intermittently in communication with the patient's respiratory tract during any form of ventilation.

4.6 apparatus internal compliance: Volume/pressure relationship of gases in those portions of the breathing system which are pressurized during the inspiratory phase time (see clause 12).

4.7 ventilator pressure, p_{vent} : Pressure of gas at a specified point in the ventilator. The site and conditions under which measurements are made should be given.

4.8 airway pressure, p_{aw} : Pressure of gas at a specified point in the patient's airway. The site and conditions under which measurements are made should be given.

4.9 alveolar pressure, p_A : Pressure of gases in the alveoli. In the case of the test lung this is represented by the pressure in the compliance chamber.

4.10 sub-atmospheric pressure; sub-ambient pressure: Pressure of gas in the breathing system lower than ambient, developed by the ventilator during the expiratory phase time.

4.11 maximum safety pressure, $p_{s,max}$: Highest gauge pressure which can be attained in the breathing system during malfunction of the ventilator but with functioning safety mechanisms.

4.12 minimum safety pressure, $p_{s,min}$: Highest numerical value of sub-atmospheric gauge pressure which can be attained in the breathing system during malfunction of the ventilator but with functioning safety mechanisms.

4.13 maximum working pressure, $p_{w,max}$: Highest numerical value of pressure which can be attained in the breathing system during the inspiratory phase when the ventilator is functioning normally.

4.14 minimum working pressure, $p_{w,min}$: Highest numerical value of sub-atmospheric gauge pressure which can be attained in the breathing system during the expiratory phase when the ventilator is functioning normally.

4.15 inspiratory triggering pressure, p_{tr} : Airway pressure at the patient connection port which must be generated by the patient to initiate the ventilator inspiratory phase.

4.16 differential inspiratory triggering pressure, Δp_{tr} : Change in airway pressure at the patient connection port which must be generated by the patient to initiate the ventilator inspiratory phase.

4.17 inspiratory triggering flow, $\dot{V}_{tr}$: Flow which must be generated by the patient at the patient connection port to initiate the ventilator inspiratory phase.

4.18 inspiratory triggering volume, V_{tr} : Volume measured at the patient connection port which must be moved by the patient to initiate the ventilator inspiratory phase.

4.19 inspiratory triggering response time, T_{tr} : Time delay between the attainment of the inspiratory triggering pressure, flow or volume requirements and the start of inspiratory flow.

4.20 inspiratory relief valve: Unidirectional valve designed to admit air to the breathing system when the patient inspires spontaneously and the supply of inspiratory gases from the ventilator is inadequate.

4.21 inspiratory relief valve resistance: Pressure difference across the inspiratory relief valve measured at a specified flow.

4.22 ventilator failure safety mechanism: Device which permits the patient to breathe ambient air during malfunction of the ventilator or failure of its gas or power supplies.