

INTERNATIONAL STANDARD

ISO
9703-1

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Anaesthesia and respiratory care alarm signals —

Part 1:

Visual alarm signals

(standards.iteh.ai)

Signaux d'alarme pour soins d'anesthésie et respiratoires —

Partie 1: Signaux d'alarme visuels

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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.

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.

International Standard ISO 9703-1 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Sub-Committee SC 3, *Lung ventilators and related equipment*.

ISO 9703 consists of the following parts under the general title *Anaesthesia and respiratory care alarm signals*:

- Part 1: *Visual alarm signals*
- Part 2: *Auditory alarm signals*

(The Introduction gives information about the future ISO 9703-2.)

Annex A of this part of ISO 9703 is for information only.

Introduction

This International Standard is the result of discussions held over a period of several years in ISO/TC 121. It addresses only the visual aspects of alarms. A working draft that addresses the audible aspects of alarm function in anaesthesia and respiratory care is presently being considered by ISO/TC 121/SC 3. When complete, it will be published as ISO 9703-2.

Medical practice in operating rooms and intensive care areas is increasingly dependent on equipment for observation and treatment of patients. Alarms are frequently used to indicate the patient's physiological status and the functional state of the equipment. The purpose of ISO 9703-1 is to define alarm categories, visual indicators, and degree of urgency. The content of this International Standard was developed with contributions from clinicians, engineers and applied psychologists. The approach taken is intended to rationalize the current situation and to limit the proliferation of different alarms in order to avoid confusion, and to minimize the distraction of hospital staff not directly responsible for devices that are in the alarmed condition.

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Anaesthesia and respiratory care alarm signals —

Part 1: Visual alarm signals

1 Scope

This part of ISO 9703 specifies the characteristics of visual alarm signals intended for use in anaesthesia and respiratory care. It takes into account the recommendations of IEC 73¹⁾.

It does not specify:

- a) the medical devices on which alarms are provided;
- b) the conditions that actuate the alarms;
- c) the means of production of the alarm signals;
- d) the allocation of priorities to alarms on medical devices;

NOTE 1 It is expected that the requirements for the application of the alarm signals specified in ISO 9703 will be included in "Particular Standards" (as formulated in IEC) for the particular medical devices.

2 Definitions

For the purposes of this part of ISO 9703, the following definitions apply.

2.1 clearly legible: Visual attribute of information displayed by the equipment that allows the operator to discern (or identify) qualitative or quantitative values or functions under a specific set of environmental conditions.

2.2 flashing frequency: Number of light flashes per unit of time.

2.3 high priority (warning) alarm: Signal indicating that immediate operator response is required.

2.4 medium priority (cautionary) alarm: Signal indicating that prompt operator response is required.

2.5 low priority (advisory) alarm: Signal indicating that operator awareness is required.

2.6 operator's position: Intended position of the operator with respect to the equipment for normal use according to the instructions for use.

3 Requirements

3.1 High priority alarm signal

A high priority signal shall have the characteristics given in table 1.

3.2 Medium priority alarm signal

A medium priority signal shall have the characteristics given in table 1.

3.3 Low priority alarm signal

A low priority signal shall have the visual characteristics given in table 1.

1) IEC 73:—, *Coding of indicating devices and actuators by means of colours and supplemental means — Requirements for safety* (forthcoming new edition of IEC 73:1984).

Table 1 — Alarm priorities and signal characteristics

Alarm category	Operator response	Meaning	Indicator colour ¹⁾	Flashing frequency ¹⁾	Duty cycle ¹⁾
High priority	Immediate response to deal with a condition	Emergency	Red	1,4 Hz to 2,8 Hz	20 % to 60 % on
Medium priority	Prompt response to deal with a condition	Abnormal	Yellow	0,4 Hz to 0,8 Hz	20 % to 60 % on
Low priority	Awareness of condition	Change of status	Yellow	Constant (on)	100 %
1) For alphanumeric or computer-generated displays, see 3.6.					

3.4 Legibility of signal

All visual signals for alarms shall be clearly legible at a distance of 1 m from the alarm indicator in a range of illumination from 100 lx to 1 500 lx by an individual with visual acuity of 1 (corrected if necessary).

3.5 Discrimination between signals

High and medium priority visual signals shall be correctly distinguished and discriminated between when tested as follows.

Position the test user so that his eyes are at a distance of 4 m from the centre of the display, perpendicular to the plane of the display, and at an angle of 30° to either side of this position. Illuminance and visual acuity shall be as in 3.4. The test is passed if the operator can correctly distinguish the high and medium priority visual signals, and can discriminate between them.

3.6 Graphic displays

Alphanumeric or computer-generated graphic displays (including centralized displays) of alarm messages are exempt from the colour and flashing frequency requirements in table 1. However, if an alphanumeric or graphics display of alarm messages does not meet the requirements of 3.4 or 3.5 as applicable, an alternative method that does meet the requirements in table 1 shall be employed.

NOTE 2 A single colour indicator per category is sufficient to satisfy this requirement.

3.7 Multiple alarm conditions

If there are multiple conditions which can cause the alarm, then the alarming condition shall be indicated.

Annex A

(informative)

Rationale statement

Subclause 3.4

The ability to see the high and medium priority visual indicators at a distance of 4 m, and to discriminate between them, is important in large

intensive-care settings with multiple ventilators and the possibility of multiple simultaneous alarms. The operator can then make a decision as to which alarm to respond to first, based on the alarm priority.

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