DRAFT INTERNATIONAL STANDARD

ISO/DIS 15002

ISO/TC **121**/SC **6**	Secretariat: **ANSI**
Voting begins on: **2022-06-21**	Voting terminates on: **2022-09-13**

Flow control devices for connection to a medical gas supply system

ICS: 11.040.10

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 15002:2022(E)

ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

Contents

Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation on the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee *121*, *Anaesthetic and respiratory equipment* Subcommittee SC 6, *Medical gas pipeline systems*.

This second edition cancels and replaces the first edition (ISO 15002:2008) and has been technically revised.

The main changes compared to the previous edition are as follows:

— Title changed to 'Flow control devices for connection to a medical gas supply system' as the requirements for *flow control devices* are the same regardless of the gas supply.

— Title changed from flow measurement to flow control as this is what they do.

— Normative and bibliography references updated.

— Layout changed from requirements for each type of *flow control device* to the common requirements as they are the same for each *flow control device*.

— Test methods put into an annex.

— Hazard identification list added as Annex D.

— The maximum flow that can be achieved when the flow control is opened fully has been included as a marking requirement on the device so that the user will know what could be delivered to the patient. A rationale has also been added to cover this marking requirement.

  — A new requirement has been added for stability of setting.
  — The environmental conditions have been aligned with IEC 60601-1-12, emergency equipment, as *flow control devices* are used in such environments.

Annex A provides additional insight into the reasoning that led to the requirements and recommendations that have been incorporated in this document. It is considered that knowledge of the reasons for the requirements will not only facilitate the proper application of this document but will expedite any subsequent revisions.

Introduction

Flow control devices are used to control the flow of gas from a medical gas supply system directly to a patient. These devices need to deliver accurate flows under varying conditions of temperature and inlet pressures. Therefore, it is important that the performance characteristics be specified and tested in a defined manner.

Flow control devices for connection to a medical gas supply system

1 Scope

1.1 This document specifies requirements for *flow control devices* that can be connected by the user either directly, by means of a probe or a *gas-specific* connector, or indirectly by means of a low-pressure hose assembly complying with ISO 5359 to:

a) a terminal unit complying with ISO 9170-1:2020 of a medical gas pipeline system complying with ISO 7396-1:2016;
b) the pressure outlet of a regulator complying with ISO 10524-1:2018; or
c) to the pressure outlet of a VIPR complying with ISO 10524-3 (see 5.2 gas inlets).

1.2 This document applies to the following types of *flow control devices*:

a) *flowmeters*;

b) *flowgauge FGCDs*: and

c) *fixed orifice FCDs*.

NOTE: *Flow control devices* that are classed as medical electrical equipment can be subject to additional requirements of IEC 60601-1[3].

1.3 This document does not apply to *flow control devices* that are:

a) for use with gases for driving surgical tools;

b) an integral part of a regulator. (See ISO 10524-1:2018); or

c) an integral part of a VIPR. (See ISO 10524-3).

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 32, *Gas cylinders for medical use — Marking for identification of content*

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

ISO 7396-1:2016, *Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum*

ISO 9170-1:2020, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum*

ISO 10524-1:2018, *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 (VIPRs)*

ISO 15001, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

ISO 17256[1], *Anaesthetic and respiratory equipment — Respiratory therapy equipment —Tubing and connectors*

ISO 18562-1, *Biocompatibility evaluation of breathing gas pathways in healthcare applications — Part 1: Evaluation and testing within a risk management process*

ISO 20417, *Information to be supplied by the manufacturer*

[1] Under development.

EN 1089-3:2011, *Transportable gas cylinders — Gas cylinder identification (excluding LPG) — Part 3: Colour coding*

CGA V5, *Diameter Index Safety System (Non-Interchangeable Low Pressure Connections for Medical Gas Applications)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at http://www.electropedia.org/

3.1 — ISO Online browsing platform: available at https://www.iso.org/obp

flow control device (FCD)

device that indicates the selected flow of a specific gas

NOTE to entry: Typical examples of *flow control devices* are given in Annex B Figure B.1.

3.2

flowgauge FCD

flow control device that measures gas pressure and that is calibrated in units of flow

NOTE to entry: *FlowgaugeFCDs*indicate flow by measuring the pressure upstream of a fixed orifice.

3. 3

flowmeter

flow control device that indicates the actual flow of gas to the patient e.g. by means of a bobbin/float within a graduated tube, or a deflected paddle

3.4

fixed orifice FCD

flow control device with a flow selector, for selecting the flow and indicating the flow selected.

3.5

gas specific

having characteristics which prevent connections between different gas services or vacuum service (Source ISO 9170-1:2020, 3.2).

3.6

rated inlet pressure, P_1

upstream pressure (or pressure range) for which the *flow control device* is designed to operate

3.7

securely attached

not detachable without the use of a too

NOTE: Defined terms are delineated throughout this document in *italic font*.

4 General requirements

Unless otherwise specified, pressures in this document are expressed as gauge pressures (i.e. atmospheric pressure is defined as 0).

4.1 Risk management

This document specifies requirements that are generally applicable to hazards associated with *flow control devices*. Manufacturers shall apply an established risk management process to the design of *flow*

control devices. (e.g. ISO 14971[7]). The risk management process shall include at least the following elements:

— risk analysis;
— risk evaluation;
— risk control;
— production process.

NOTE: See Annex D for a list of hazards that can be used as guidance in the risk management process.

Check conformance by inspection of the risk management file.

4.2 Usability

Manufacturers shall apply a usability engineering process to assess and mitigate any hazards caused by usability problems associated with correct use (i.e. normal use) and use errors (e.g. IEC 60601-1-6[3]) and IEC 62366-1[4]).

Check conformance by inspection of the usability engineering file.

4.3 Clinical evaluation

Where appropriate, clinical studies shall be performed under the conditions for which performance is claimed and documented in the risk management file.

NOTE: Clinical data may be sourced from:

— clinical investigation(s) of the device concerned,
— clinical investigation(s) or other studies reported in the scientific literature of a similar device for which equivalence to the device in question can be demonstrated, or
— published and/or unpublished reports on other clinical experience with either the device in question or a similar device for which equivalence to the device in question can be demonstrated.

Check conformance by inspection of the technical file.

Inclusion of this clause is due to be considered by SC 6

4.4 Materials

4.4.1 Materials shall be resistant to corrosion and compatible with the gases with which they are designed to be used under the environmental conditions specified in 4.6.

NOTE: Corrosion resistance includes resistance against moisture and surrounding materials.

Check conformance by inspection of the technical file.

4.4.2 Materials in the breathing gas pathway shall be evaluated for biocompatibility according to ISO 18562-1.

NOTE: ISO 18562-1 also refers to other parts of the 18562 series of standards for biocompatibility evaluation of particulates, volatile organic compounds and leachables.

Inclusion of this clause is Due to be considered by SC6

Check conformance by inspection of the technical file.

4.4.3 Materials shall be resistant to deterioration by cleaning and disinfection or sterilization methods recommended by the manufacturer [see 7.3 h)].

Check compliance by inspection of the technical file.

~~**4.4.4** The selection of materials shall include a systematic review of their carcinogenic, mutagenic or toxic to reproduction ('CMR') or endocrine-disrupting properties.~~

~~For those materials present in excess of 0,1 % (w/w) in any parts, a safer alternative should be used.~~

~~If no suitable alternative exists, the risk for patient or user shall be assessed taking into account the intended use and latest relevant scientific committee guidelines.~~

~~Check compliance by inspection of the technical file and the risk management file.~~

To be deleted if 4.4.2 is retained

4.5 Oxygen compatibility

NOTE : There is rational for this requirement in Annex A, (see A.4.5).

Components and lubricants used during the manufacture of *flow control devices* that come into contact with medical gases during normal use shall meet the compatibility requirements of ISO 15001.

NOTE: This applies to all *flow control devices* even though ISO 15001 is specifically for oxygen compatibility.

Check conformance by inspection of the technical file.

4.6 Environmental conditions

NOTE: There is rationale for this requirement in Annex A. (see A.4.6).

4.6.1 Transport and storage

4.6.1.1 Unless otherwise indicated in the instructions for use *flow control devices* shall comply with the requirements specified in Clause 5 after being exposed, whilst packed for transport and storage, to the following environmental conditions:

a) −40 °C to +5 °C without relative humidity control;
b) +5 °C to +35 °C at a relative humidity up to 90 %, non-condensing; and
c) >35 °C to 70 °C at a water vapour pressure up to 50 hPa.

Check conformance by the tests given in Annex C.

4.6.1.2 If the instructions for use state a more restricted range of environmental transport and storage conditions between uses, these environmental conditions shall be:

a) justified in the risk management file; and
b) marked on the equipment. If not practicable in the instructions for use.

Check conformance by inspection of the risk management file and the visual inspection of the device or the instructions for use.

4.6.2 Operating conditions

Unless otherwise indicated in the instructions for use *flow control devices* shall comply with the design requirements specified in Clause 5 when operated under the following environmental conditions:

a) a temperature range of 0 °C to +40 °C; and
b) an atmospheric pressure range of 620 hPa to 1 060 hPa.

If the instructions for use state a more restricted range of environmental operating conditions, these environmental conditions shall be:
– justified in the risk management file; and
– marked on the equipment. If not practicable in the instructions for use;.

Check conformance by inspection of the risk management file and the visual inspection of the device or the instructions for use.

4.7 Alternative construction

Flow-metering devices, and components or parts thereof, using materials or having forms of construction different from those detailed in this document (except for dimensions and allocation of DISS, NIST and SIS connectors and probes used as inlet connectors), shall be presumed to be in compliance with the safety objectives of this document if it can be demonstrated that an equivalent degree of safety is obtained (i.e. compliance with requirements presumes that risks have been mitigated to acceptable levels) unless objective evidence to the contrary becomes available.

NOTE 1 Objective evidence can be obtained by postmarket surveillance

NOTE 2 Regional or national regulations can require the provision of evidence to a competent authority or conformity assessment body upon request.

Check conformance by providing evidence of an equivalent degree of safety upon request.

5 Design requirements

5.1 General

Flow control devices shall be fitted with a means to prevent particles larger than 100μm from entering the gas pathway.

Check conformance by inspection of the technical file.

5.2 Gas inlets

Gas inlets shall be *securely attached* to the *flow control device* and be either:

a) a probe complying with ISO 9170-1 [e.g. see Figure B.2 a)];

NOTE: ISO 9170-1 does not specify the design or the dimensions of *probes*, that is the domain of National standards.

b) the nut and nipple of a *gas-specific* screw-threaded connector in accordance with National or regional standards (i.e. DISS, NIST or SIS) [e.g. see Figure B.2 b)], or
c) a *gas specific* low-pressure flexible hose assembly complying with ISO 5359 [for examples see Figures B.2 c) and B.2 d)].

Check conformance by inspection of the technical file.

5.3 Outlet connectors

Outlet connectors shall be one of the following:

a) a *securely attached* nipple complying with ISO 17256; or
b) a *gas-specific* threaded male DISS connector complying with CGA V5.

NOTE: CGA V5 is referenced as ISO 17256 specifies threaded DISS connectors for oxygen and air only.

Check conformance by inspection of the technical file.

5.4 Mechanical strength

NOTE: There is rationale for this requirement in Annex A, (see A.5.4).

Flow control devices shall meet requirements leakage (5.5) and accuracy (5.6.4) after being subjected to an inlet pressure of 1200 kPa for ≥ 5 mins.

Check conformance by the test given in C.2.

5.5 Leakage

NOTE: There is rationale for this requirement in Annex A (see A.5.5).

5.5.1 The internal leakage shall not exceed 0,3 ml/min at the *rated inlet pressure P1*, specified by the manufacturer (see 7.3 b)) when the flow control is closed with a torque 0,4 Nm or the means of flow selection for multiple fixed orifices is set to zero.

Check conformance by the test method given in C.3.

5.5.2 The external leakage (to atmosphere) shall not exceed 0,5 ml/min at the *rated inlet pressure* P_1 when the outlet is plugged and the flow control is opened fully or the means of flow selection for multiple fixed orifices set to the maximum setting.

Check conformance by the test method given in C.3.

5.6 Flow indication

5.6.1 *Flow control devices* shall be provided with a means to indicate the selected flow.