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Flow control devices for connection to a medical gas supply system

Dispositifs de contrôle du débit pour raccordement à un système d'alimentation en gaz médicaux

Reference number
ISO 15002:2023(E)

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

This third edition cancels and replaces the second edition (ISO 15002:2008), which has been technically revised. It also incorporates the Amendment ISO 15002:2008/Amd.1:2018.

The main changes are as follows:

— title changed as the requirements for *flow control devices* are the same regardless of the gas supply and they control the flow, they do not measure the flow;

— 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 have been rationalised and put into a new Annex C;

— hazard identification list added as a new 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; and

— the requirement for accuracy has been rationalised for clarity.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html

Introduction

Flow control devices are used to administer a prescribed flow of gas to a patient interface device (e.g. nasal cannula, facemask) from a pressure gas source, such as a medical gas supply system. 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.

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.

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 conforming with ISO 5359 to:

a) a terminal unit conforming with ISO 9170-1 of a medical gas pipeline system conforming with ISO 7396-1:2016;

b) the pressure outlet of a regulator conforming with ISO 10524-1:2018; or

c) to the pressure outlet of a valve integrated pressure regulator (VIPR) conforming with ISO 10524-3 (see 5.2 gas inlets).

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

a) *flowmeters*;

b) *flowgauge FCDs*; 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.

1.3 This document applies to *flow control devices* for the following gases:

— oxygen;

— oxygen 93 %;

— nitrous oxide;

— medical air;

— carbon dioxide;

— oxygen/nitrous oxide mixture 50/50 (% volume fraction);

— oxygen-enriched air;

— helium;

— xenon; and

— specified mixtures of the gases listed above.

NOTE *Flow control devices* can be available for other gases.

1.4 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 valve with integrated pressure regulator (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, *Anaesthetic and respiratory equipment — 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 9170-1:2017, *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 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, *Medical devices — Information to be supplied by the manufacturer*

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 terminology databases for use in standardization at the following addresses:

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

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

NOTE The terms defined in Clause 3 are delineated throughout this document in *italic font*.

3.1
flow control device
FCD
device that indicates the selected flow of a specific gas

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

1) Under preparation. Stage at the time of publication: ISO/DIS 17256:2023.

3.2
flowgauge FCD
flow control device that measures gas pressure and that is calibrated in units of flow

Note 1 to entry: *Flowgauge FCDs* 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 9170-1:2017, 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 tool

4 General requirements

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

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). The risk management process should include at least the following elements:

— risk analysis;

— risk evaluation;

— risk control; and

— production and post-production information.

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 and IEC 62366-1).

Check conformance by inspection of the usability engineering file.

4.3 Materials

4.3.1 Materials shall be resistant to corrosion and designed to withstand the environmental conditions specified in 4.5.

Check conformance by inspection of the technical file.

4.3.2 Materials shall be compatible with the gases with which they can come into contact.

NOTE ISO 11114-1 and ISO 11114-2 can offer helpful guidance on material compatibility with gases.

Check conformance by inspection of the technical file.

4.3.3 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 for biocompatibility evaluation of particulates, volatile organic compounds and leachables.

Check conformance by inspection of the technical file.

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

Check conformance by inspection of the technical file.

4.3.5 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 conformance by inspection of the technical file and the risk management file.

4.4 Oxygen compatibility

NOTE There is rationale for this subclause in A.2.

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.

Check conformance by inspection of the technical file.

4.5 Environmental conditions

NOTE There is rationale for this subclause in A.3.

4.5.1 Transport and storage environmental conditions

4.5.1.1 Unless different environmental conditions for transport and storage are stated by the manufacturer in their instructions for use [see 7.3 i)] *flow control devices* shall comply with the performance 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.

NOTE Performance requirements include: mechanical strength (5.4); leakage (5.5); accuracy (5.7) and stability of indicated flow (5.8)

Check conformance by the tests given in Annex C.

4.5.1.2 If manufacturers state a different range of environmental transport and storage conditions in their instructions for use they shall:

a) justify these transport and storage environmental conditions in their risk management file;

b) mark these transport and storage environmental conditions on the packaging; and

c) comply with the performance requirements specified in Clause 5 after being exposed, whilst packed for transport and storage, at these environmental conditions.

NOTE Performance requirements include: mechanical strength (5.4), leakage (5.5), accuracy (5.7) and stability of indicated flow (5.8)

Check conformance by:

— inspection of the risk management file;

— visual inspection of the packaging; and

— by performing the tests given in Annex C.

4.5.2 Operating environmental conditions

4.5.2.1 *Flow control devices* shall comply with the performance requirements specified in Clause 5 when operated under normal environmental conditions [i.e. a temperature of (23 ± 3) °C and an atmospheric pressure of 101,3 kPa].

NOTE Performance requirements include: mechanical strength (5.4), leakage (5.5), accuracy (5.7), stability of indicated flow (5.8) and continuous increase in flow (5.9).

Check conformance by the tests given in Annex C.

4.5.2.2 Manufacturers shall state, in their instructions for use, [see 7.3 e)], any adverse effects on the performance of their *flow control device* when subjected to the following operating 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.

Check conformance by inspection of the instructions for use.

5 Design requirements

5.1 General

Flow control devices shall be fitted with a means to prevent particles larger than 100 μm 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 9170-1:2017 [e.g. see Figure B.2 a)];

NOTE ISO 9170-1:2017 does not specify the design or the dimensions of *probes*.

b) the nut and nipple of a *gas-specific* screw-threaded connector in accordance with a recognized system [e.g. diameter-indexed safety system (DISS), non-interchangeable screw-threaded (NIST) or sleeve indexed system (SIS), e.g. see Figure B.2 b)]; or

c) a *gas specific* low-pressure flexible hose assembly complying with ISO 5359 [e.g. 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 1 CGA V5 is referenced as ISO 17256 specifies threaded DISS connectors for oxygen and air only.

NOTE 2 A user-detachable adaptor can be used to convert the threaded outlet to a nipple as specified in ISO 17256.

Check conformance by inspection of the technical file.

5.4 Mechanical strength

NOTE There is rationale for this subclause in A.4.

Flow control devices shall withstand an inlet pressure of ≥1 200 kPa for ≥5 min without adversely affecting performance when tested under normal operating environmental conditions.

Check conformance by the test given in C.6.

5.5 Leakage

NOTE There is rationale for this subclause in A.5.

5.5.1 The internal leakage shall not exceed 0,3 ml/min at the *rated inlet pressure* P_1, specified by the manufacturer [see 7.3 b)] when the flow control is closed with a torque 0,4 Nm or the flow selector for multiple fixed orifices is set to zero.

Check conformance by the test method given in C.7.

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 flow selector for multiple fixed orifices set to the maximum setting.

Check conformance by the test method given in C.7.

5.6 Flow indication

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

Check conformance by visual inspection.

5.6.2 Flow shall be indicated in either l/min or ml/min as appropriate.

Check conformance by visual inspection.

5.6.3 *Flowmeters* that can be adjusted to provide flows greater than that indicated on the scale shall be marked with the maximum flow that can be set [see 7.2 f)]. The manufacturer shall also indicate in the instructions for use and on the device the *rated inlet pressure* P_1 [see 7.3 b) and 7.2 c)] at which this flow is determined.

NOTE Ungraduated and therefore unknown high flows can be dangerous particularly for neonatal and paediatric patients.

Check conformance by visual inspection.

5.7 Accuracy

NOTE There is rationale for this subclause in A.5.

5.7.1 The accuracy of the actual flowrate at any graduation/flow setting shall be measured at the *rated inlet pressure* P_1 specified by the manufacturer, [see 7.3 b)], when the flow is discharged into ambient atmosphere and corrected, if appropriate, to reference conditions (see C.4).

Check conformance by inspection of the technical file.

5.7.2 The accuracy of the actual flowrate at each graduation/flow setting:

a) for *flowmeters* and *flowgauge FCDs* with a maximum flow setting ≤5 l/min, shall be within ±10 % of the maximum flow setting indicated on the scale.

   (e.g. for a *flowmeter* with a maximum flow setting of 3 l/min, the actual flow at each flow setting of the *flowmeter,* shall be within ± 0,3 l/min of the selected flow setting);

b) for *flowmeters and flowgauge FCDs* with a maximum flow setting >5 l/min, shall be within ±0,5 l/min of the flow setting up to 5 l/min and within ±10 % of the selected flow setting over 5 l/min.

   (e.g. for a *flowmeter* with a maximum flow setting of 15 l/min, the actual flowrate at a flowrate setting of 4 l/min shall be between 3,5 and 4,5 l/min, and at 10 l/min shall be between 9,0 and 11,0 l/min).

c) for *fixed orifice FCDs*, with flow settings ≤1,5 l/min, the actual flowrate shall be within ±30 % of the selected flow setting and for each flow setting >1,5 l/min, the actual flowrate shall be within ±20 % of the selected flow setting.

NOTE The position of the flow control/selector in relation to the means of flow indication can affect the accuracy of flow at different supply pressures and resistance in the output.

Check conformance by the test given in C.8.

5.7.3 If electrostatic charges can affect the accuracy there should be a means to minimize any build-up of electrostatic charges.

5.8 Stability of indicated flow

NOTE There is rationale for this subclause in A.6.

Flow control devices shall, once set at a flow, not deviate from that setting by more than ±10 % over a period of 1 hour.

Check conformance by the test given in C.9.

5.9 Continuous increase in flow

NOTE There is rationale for this subclause in A.7.

For all *flow control devices*, there shall be an increase in the flow of medical gas throughout the full-scale range of the flow control device when the flow is adjusted from zero to the maximum flow that the device is intended to deliver.

Check conformance by the test given in C.9.

5.10 Security of components

Flow control device components shall be *securely attached* to prevent them from being removed by the user.

NOTE *Flowmeter* flow tubes are exempt from this requirement.

Check conformance by inspection of the technical file.

5.11 Flow controls and flow selectors

5.11.1 *Flowmeter* and *flowgauge FCD* flow controls shall turn anti-clockwise to increase the flow.

NOTE There is rationale for this subclause in A.8.

Check conformance by functional testing.

5.11.2 Fixed orifice flow selectors shall be marked with an appropriate symbol (see 7.2 d) to indicate the direction to increase or decrease the flow.

NOTE There is rationale for this subclause in A.8.

Check conformance by visual inspection.

5.11.3 Flow selectors for *fixed orifice FCDs* shall be designed:

a) with a means to self-centre on a graduated flow;

NOTE 1 This is to prevent the selection of positions of no flow between adjacent settings.

b) so that they cannot be set above the maximum setting; and

c) so that the tangential force required at the maximum radius of a rotary flow selector to change from the off/zero position and from one setting to another shall be >5 N and <50 N.

NOTE 2 There is rationale for this subclause in A.9.

Check conformance by functional testing.

5.11.4 *Fixed orifice FCDs* that are designed to provide a flow, when set between graduated settings, shall conform with 5.9.

Check conformance by functional testing.

6 Packaging

Flow control devices shall be packaged to protect against particulate contamination and damage during storage and transportation.

Check conformance by inspection of the technical file.

7 Information supplied by the manufacturer

7.1 General

Information supplied by the manufacturer shall comply with ISO 20417.

7.2 Marking

Marking on *flow control devices* shall, in addition to the requirements in ISO 20417, include the following:

a) the symbol of the relevant gas in accordance with Table 1;

b) in addition to the symbol, the name of the gas and colour coding can be used. If colour coding is used it shall be either the colour coding specified in Table 1 or the variations given in ISO 32;

Table 1 — Medical gases, names, symbols and colour coding

Name	Symbol	Colour coding
Medical air	Air	Black-white [a]
Oxygen/O2 93	O_2	White [a]
Nitrous oxide	N_2O	Blue [a]
Carbon dioxide	CO_2	Grey [a]
Helium	He	Brown [a]
Xenon	Xe	Bright green [b]
Mixture of above gases	[c]	[c]

NOTE The word air can be expressed in the relevant National language.

[a] In accordance with ISO 32.

[b] In accordance with EN 1089-3:2011, Table A.1.

[c] In accordance with the mixture components.

c) the *rated inlet pressure* P_1 at which the *flow control device* has been calibrated;

d) for *fixed orifice FCD* flow selectors a symbol to indicate the direction for increasing and decreasing the flow;

e) point on the indicator for reading the flow, where appropriate;

f) for *flowmeters and flowgauge FCDs* the maximum flow when the flow control valve is fully open; (see 5.6.3);

NOTE 1 There is rationale for this subclause in A.10.

g) if practicable, the operating environmental conditions (see 4.5.2)

h) if appropriate, a warning to use no oil.

NOTE 2 This only applies to *flow control devices* designed for use with oxygen or oxygen mixtures.

Check conformance by visual inspection.

7.3 Instructions for use

Flow control devices shall be accompanied with instructions for their safe use, which in addition to the requirements given in ISO 20417, shall include the following:

a) for *flow control devices* designed for use with oxygen or oxygen mixtures a warning of the dangers of fire arising from use of lubricants not recommended by the manufacturer;

b) the *rated inlet pressure* P_1;

c) the effect of varying resistance downstream of the outlet, (e.g. therapy tubing), on the accuracy of flow;

d) the effect of varying inlet pressure on the accuracy of flow;

e) any adverse effects on the performance when subjected to the operating environmental conditions specified in 4.5.2;

f) for *fixed orifice FCDs* with multiple fixed orifices, a warning to the effect that the graduated scale does not indicate that gas is flowing;

g) for *flowmeters* a warning to the effect that they must be kept in a vertical position when in use;

h) the recommended cleaning and disinfection or sterilization methods; and

i) the recommended environmental conditions for transport and storage.

Check conformance by inspection of the instructions for use.

Annex A
(informative)

Rationale

A.1 General

This annex provides a rationale for some requirements of this document and is intended for those who are familiar with the subject of this document but who have not participated in its development. An understanding of the rationale underlying these requirements is considered to be essential for their proper application. Furthermore, as clinical practice and technology change it is believed that a rationale will facilitate any revision of this document necessitated by those developments.

A.2 Subclause 4.4 – Oxygen compatibility

Flow control devices for different gases are often made with interchangeable components or subassemblies. The requirement for compatibility with oxygen should therefore be applied to *flow control devices* for all gases.

The auto-ignition temperature of non-metallic components that come into contact with the gas, including sealing materials and lubricants should, according to ISO 15001, be no lower than 150 °C.

A.3 Subclause 4.5 – Environmental conditions

The environmental conditions have been aligned with IEC 60601-1-12 as *flow control devices* are often used in emergency environments. Humidity is not considered to affect *flow control devices* so is not specified for environmental operating conditions.

A.4 Subclause 5.4 – Mechanical strength

1 000 kPa is the maximum allowable pressure that can be reached under single fault conditions for a *medical gas pipeline system* complying with ISO 7396-1 and the situation can last 5 min or more. The general principle for mechanical strength is to include a safety factor which has been set at 1,2 in this case, the same as for terminal units in ISO 9170-1.

A.5 Subclauses 5.5 and 5.7 – Leakage and accuracy

As nominal medical gas pipeline pressures can vary between countries the leakage and accuracy requirements have been specified at the *rated inlet pressure* P_1 specified by the manufacturer. There are also statements specified in the instructions for use warning the user that changes in inlet pressure can affect the accuracy of the *flow control device.*

A.6 Subclause 5.8 – Stability of indicated flow

Flowmeters and flowgauge FCDs with flow control valves made with viscoelastic materials can result in the flow reducing over time after the flow control/selector is opened from being tightly closed. *Fixed orifice FCDs* with flow control orifices made from a viscoelastic material may reduce the flow over time once the flow selector has been opened.

A.7 Subclause 5.9 – Continuous increase in flow

Where the increment between adjacent flow settings of a *fixed orifice FCD* is small, there arises the potential for an intended increase in flow to result in an actual decrease in flow where the upper and lower tolerance limits of adjacent settings overlap. The vice versa is also possible. This must be avoided because clinical decisions can take into account the physiological response an increase or decrease in medical gas flow and an unintentional opposite adjustment of flow to that intended can confound a patient assessment.

A.8 Subclauses 5.11.1 and 5.11.2 – Flow control/selector direction to increase flow

The direction of flow for flow controls for *flowmeters* and *flowgauge FCDs* has been continued from the 2008 version of this document as it is the convention clinicians are used to for increasing flow. However, rotation of flow selectors on *fixed orifice FCDs* can now be in either direction as long as the direction to increase and decrease the flow is clearly marked.

A.9 Subclause 5.11.3 – Setting of flow selector between graduations

A dangerous situation could arise if the flow selector of a *fixed orifice FCD* can be unintentionally set to a position between graduations especially where no flow occurs. The design of the *flow control device* ought to prevent this from happening.

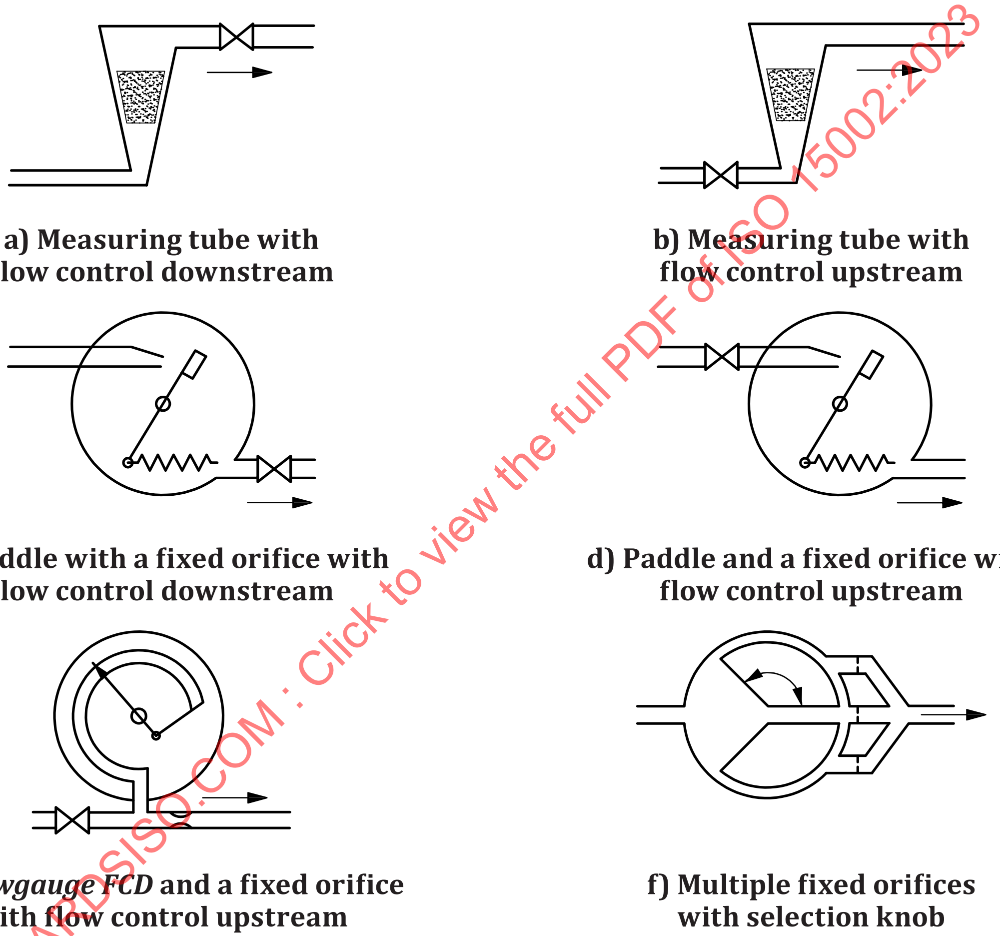
A.10 Subclause 7.2 f) – Maximum flow marking

This new marking requirement has been included following extensive discussions within the SC 6 working group following an attempt to address this issue through two amendments. It was felt that instead of restricting the maximum flow where the user may still not be aware of the flow being given to the patient, it was better to indicate the maximum flow on the device to make the user fully aware of the flow being given to the patient.

Annex B
(informative)

Examples of *flow control devices* and gas supply inlets

B.1 Examples of *flow control devices*



a) Measuring tube with flow control downstream

b) Measuring tube with flow control upstream

c) Paddle with a fixed orifice with flow control downstream

d) Paddle and a fixed orifice with flow control upstream

e) *Flowgauge FCD* and a fixed orifice with flow control upstream

f) Multiple fixed orifices with selection knob

Figure B.1 — Examples of *flow control devices*

Figure B.1 a) shows a *flowmeter* which comprises a vertical measuring tube whose cross-section increases upwards and in which a float is lifted by the action of the gas flow. The float settles at a height which is a function of the flow, which is controlled by a flow control fitted downstream of the tube.

Figure B.1 b) shows the same *flowmeter* as in a) with the flow control fitted upstream of the tube.

Figure B.1 c) shows a *flowmeter* which comprises a paddle connected to a return spring which is located at the outlet of a fixed orifice. The paddle is pushed by the action of the gas flow and settles at a position which is a function of the flow that is controlled by a flow control fitted downstream of the orifice.

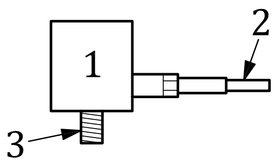
Figure B.1 d) shows the same *flowmeter* as in c) with the flow control fitted upstream of the orifice.

Figure B.1 e) shows a *flowgauge FCD* which comprises a pressure gauge measuring the pressure upstream of a fixed orifice. The pressure is a function of the flow, which is controlled by a flow control fitted upstream of the pressure gauge.

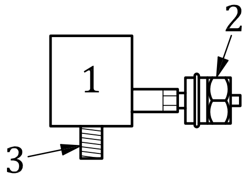
Figure B.1 f) shows a *fixed orifice FCD* which comprises multiple fixed orifices. The change from the “off” position and from one setting to another can be achieved, for example, by turning a knob.

B.2 Examples of gas supply inlets

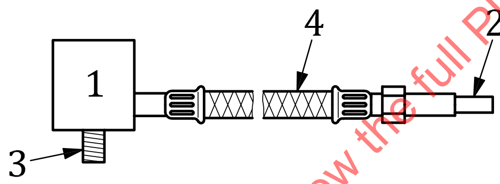
Figure B.2 shows examples of gas supply inlets.



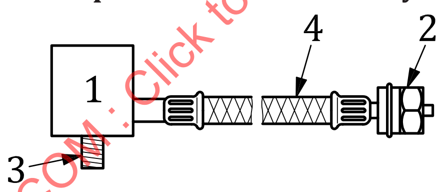
a) *Flow control device* with a probe gas supply inlet



b) *Flow control device* with a DISS, NIST, SIS nut and nipple gas supply inlet



c) *Flow control device* with a low-pressure hose assembly with probe gas supply inlet



d) *Flow control device* with a low-pressure hose assembly and a DISS, NIST or SIS nut and nipple gas supply inlet

Key

1 *flow control device*

2 gas supply inlet

3 outlet connector

4 low-pressure hose assembly

Figure B.2 — Examples of gas supply inlets

Annex C
(normative)

Test methods

C.1 General

C.1.1 All tests are type tests and shall be carried out on three samples as follows:

C.1.2 Samples 1, 2 and 3 shall be tested for leakage (see C.3), accuracy (see C.4), stability of setting (see C.5) and continuous increase (see C.6) at ambient test conditions (see C.3.1);

C.1.3 Samples 1 and 2 shall then be pre-conditioned, according to C.1.2, then tested for leakage (see C.3), accuracy (see C.4), stability of setting (see C.5) and continuous increase (see C.6);

C.1.4 Samples 1 and 3 shall then be tested for mechanical strength (see C.2) before being tested for leakage (see C.3), accuracy (see C.4), stability of setting (see C.5) and continuous increase (see C.6).

C.2 Pre-conditioning

Those test samples to be preconditioned (see C.1.3) shall, whilst in their packaging for transport and storage, be exposed to the extremes of the environmental conditions for transport and storage specified in 4.5.1.1 a) and c) or at the extremes of the environmental conditions for transport and storage specified by the manufacturer in their instructions for use, for ≥12 h.

C.3 Test conditions

C.3.1 Tests shall be carried out at ambient conditions [i.e. a temperature of (23 ± 3) °C and an atmospheric pressure of 101,3 kPa].

C.3.2 Tests shall be carried out using either the medical gas for which the *flow control device* is designed or using air or nitrogen. Gases shall be clean, oil-free with a dew point of -48 °C at atmospheric pressure.

C.4 Reference conditions

If a *flow control device* is tested with air or nitrogen instead of the medical gas for which it is intended, the flows shall be corrected, to a temperature of 23 °C of and an atmospheric pressure of 101,3 kPa, using the conversion coefficients given in Table C.1 and the flow of intended gas is equal to the flow of test gas multiplied by the conversion coefficient.

Table C.1 — Conversion coefficients

Intended gas [a]	Conversion coefficient	
	Test gas air	Test gas nitrogen
Air	1	0,98
Oxygen	0,95	0,93
Nitrogen	1,02	1
Nitrous oxide	0,81	0,79
Carbon dioxide	0,81	0,79
Helium	2,69	2,65
Xenon	0,47	0,46

C.5 Apparatus

The resolution and accuracy of all measuring test equipment shall be within ±3 % of the measured value.

C.6 Test method for mechanical strength (see 5.4)

C.6.1 Principle

Test samples 1 and 3 are subjected to an internal static pressure equivalent to the maximum pressure that can be generated by a *medical gas pipeline system* under single fault condition with an additional safety factor to ensure that if the outlet is blocked it can physically withstand such a pressure and not cause any harm.

C.6.2 Apparatus

a) Pressure generator capable of producing a pressure >1 200 kPa.

b) Timing device.

C.6.3 Procedure

a) Plug the outlet and set the flow selector to the maximum indicated flow.

b) Subject the test samples to an inlet pressure of (1 200 ± 10) kPa and hold for ≥ 5 min.

c) Verify that the test samples meet the requirements in 5.4.

C.7 Test method for leakage (see 5.5)

C.7.1 Principle

Test samples 1, 2 and 3 are tested to see if they leak internally, or externally to atmosphere, when subjected to the *rated inlet pressure* P_1 at ambient environmental conditions.

Test samples 1 and 2 are further tested for leakage after being pre-conditioned according to C.2.

Test samples 1 and 3 are further tested for leakage following the mechanical strength test given in C.6.

C.7.2 Apparatus

a) Pressure generator capable of producing a pressure greater than the *rated inlet pressure* P_1.

b) Timing device.

c) Flow measuring device.

C.7.3 Procedure for internal leakage (see 5.5.1)

C.7.3.1 For samples 1, 2 and 3 at ambient conditions

a) Set the flow selectors to off or zero.

b) Subject the test samples to an internal static pressure equal to the *rated inlet pressure* P_1 and hold for ≥5 min.

c) Verify that the test samples meet the leakage requirements specified in 5.5.1.

C.7.3.2 Procedure for samples 1 and 2 after preconditioning

a) Pre-condition test samples 1 and 2 (see C.2).

b) Repeat the test procedure given in C.7.3.1.

C.7.3.3 Procedure for samples 1 and 3 after mechanical strength test

Following the mechanical strength test on samples 1 and 3 (see C.6) repeat the test procedure given in C.7.3.1.

C.7.4 Procedure for external leakage (see 5.5.2)

C.7.4.1 For samples 1, 2 and 3 at ambient conditions

a) Plug the outlet of the test samples.

b) Set the flow selector to the maximum graduated flow setting.

c) Subject the test samples to an internal static pressure equal to the *rated inlet pressure* P_1 and hold that pressure for ≥5 min.

d) Verify that the *flow control device* meets the leakage requirements specified in 5.5.2.

C.7.4.2 Procedure for samples 1 and 2 after preconditioning

a) Pre-condition test samples 1 and 2 (see C.2).

b) Repeat the test procedure given in C.7.4.1.

C.7.4.3 Procedure for samples 1 and 3 after mechanical strength test

a) Subject samples 1 and 3 to the mechanical strength test given in C.6.

b) Repeat the test procedure given in C.7.4.1.

C.8 Test method for accuracy of graduations (see 5.7)

C.8.1 Principle

The accuracy of each calibrated flow setting/graduation is verified by subjecting the *flow control device* to a static internal pressure equal to the *rated inlet pressure* P_1 then checking that the actual flow corrected to the reference conditions (see C.1.3) is within the accuracy tolerance specified.

C.8.2 Apparatus

a) Pressure generator capable of producing a pressure greater than the *rated inlet pressure* P_1.

b) Flow measuring device.

C.8.3 Procedure

C.8.3.1 Procedure for samples 1, 2 and 3 at ambient conditions

a) Subject the test samples to an internal static pressure equal to the *rated inlet pressure* P_1.

b) Verify that the actual flow is within the tolerances specified in 5.7.2 for each calibrated flow when corrected to the reference conditions, if applicable, specified in C.4.

C.8.3.2 Procedure for samples 1 and 2 after preconditioning

a) Pre-condition test samples 1 and 2 (see C.2).

b) Repeat the test procedure given in C.8.3.1.

C.8.3.3 Procedure for samples 1 and 3 after mechanical strength test

a) Subject samples 1 and 3 to the mechanical strength test given in C.6.

b) Repeat the test procedure given in C.8.3.1.

C.9 Test method for stability of indicated flow (see 5.8) and continuous increase in flow (see 5.9)

C.9.1 Principle

Drift from the set flow is checked by setting a flow and then checking whether this has moved by more than a specified amount. The *flow control device* is first tested when the flow selector is off/zero and then tested at the minimum and maximum calibrated settings to allow for different materials at ambient conditions. The requirement for a continuous increase in flow can be tested at the same time.

C.9.2 Apparatus

a) Pressure generator capable of producing a pressure greater than the *rated inlet pressure* P_1.

b) Timing device.

c) Torque wrench.

d) Flow measuring device.

C.9.3 Procedure for *flowmeters* samples 1, 2 and 3 under ambient conditions

a) Connect each test flowmeter sample to the pressure generator and supply an inlet pressure equal to the *rated inlet pressure* P_1.

b) Set the flow selector to the mid position of the calibrated graduations and leave for >1 h.

c) Verify that the reading has not drifted by more than that specified in 5.8.

d) Repeat a) and b) but at the maximum calibrated graduation.

e) Verify that the flow increases when the flow selector is moved from the minimum to the maximum calibrated graduation.