INTERNATIONAL STANDARD

ISO 10524

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Pressure regulators and pressure regulators with flow-metering devices for medical gas systems

Régulateurs de pression avec ou sans débitmètre pour systèmes de gaz médicaux

Reference number
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Contents

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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 10524 was prepared by Technical Committee ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC 6, *Medical gas systems*.

Annex A of this International Standard is for information only.

Introduction

Pressure regulators are widely used on medical gas cylinders to reduce the high cylinder pressure to a lower pressure suitable for use with medical equipment or for delivery of the gas directly to a patient. They may be used to control pressure and flow supplied by a medical gas pipeline system.

These functions cover a wide range of inlet and outlet pressures and flows which require specific design characteristics for the appropriate regulator. It is therefore important that the operating characteristics of the pressure regulator be specified and tested in a defined manner.

Pressure regulators are normally coupled to devices which control the flow, such as a flow-control valve or a fixed orifice; the flow may be indicated by a flow-gauge or by a flowmeter.

It is essential that regular inspection and repair are undertaken to ensure that the pressure regulators continue to meet the requirements of this International Standard.

This International Standard pays particular attention to

— safety (mechanical strength, safe relief of excess pressure and resistance to ignition);

— cleanliness and suitability of materials;

— gas specificity;

— identification;

— testing;

— information supplied.

Pressure regulators and pressure regulators with flow-metering devices for medical gas systems

1 Scope

1.1 This International Standard specifies requirements for pressure regulators and pressure regulators with flow-metering devices intended for the administration of medical gases in the treatment, management, diagnostic evaluation and care of patients. It applies to the types of pressure regulators given in a), b) and c) for use with the following medical gases:

air
carbon dioxide
helium
oxygen
nitrogen
nitrous oxide
xenon
mixtures of oxygen and carbon dioxide
mixtures of oxygen and helium
mixtures of oxygen and nitrogen
mixtures of oxygen and nitrous oxide

The types of pressure regulators are as follows:

a) high-pressure regulators (inlet pressure up to 20 000 kPa) intended to be connected by the user to high-pressure gas cylinders;

b) high-pressure regulators (inlet pressure up to 20 000 kPa) that are an integral part of medical equipment (e.g. anaesthetic machines, lung ventilators, resuscitators);

c) low-pressure regulators (inlet pressure up to 1 400 kPa) intended to be connected by the user to terminal units of medical gas pipeline systems.

This International Standard also applies to the following types of pressure regulators with flow-metering devices:

d) pressure regulators with integral flow-metering devices as described in a) and c);

e) pressure regulators with flow-metering devices that are not integral with the types of pressure regulators described in a) and c) but are not intended to be detached from the pressure regulator by the user.

1.2 This International Standard does not apply to

a) high-pressure and low-pressure regulators that are an integral part of medical gas pipeline systems;

b) low-pressure regulators, with or without flow-metering devices, that are an integral part of medical equipment;

c) pressure regulators integrated within cylinder valves;

d) vacuum regulators.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below.

Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 7-1:1994, *Pipe threads where pressure-tight joints are made on the threads — Part 1: Dimensions, tolerances and designation.*

ISO 32:1977, *Gas cylinders for medical use — Marking for identification of content.*

ISO 228-1:1994, *Pipe threads where pressure-tight joints are not made on the threads — Part 1: Dimensions, tolerances and designation.*

ISO 261:—[1], *ISO general-purpose metric screw threads — General plan.*

ISO 407:1991, *Small medical gas cylinders — Pin-index yoke-type valve connections.*

ISO 554:1976, *Standard atmospheres for conditioning and/or testing — Specifications.*

ISO 5145:1990, *Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning.*

ISO 5171:1995, *Pressure gauges used in welding, cutting and allied processes.*

ISO 5359:1989, *Low-pressure flexible connecting assemblies (hose assemblies) for use with medical gas systems.*

ISO 9170:1990, *Terminal units for use in medical gas pipeline systems.*

3 Definitions

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

3.1 pressure regulator: Gas pressure reducing and controlling device designed to provide a constant delivery (downstream) pressure over a range of inlet pressures and flows.

3.2 adjustable pressure regulator: Pressure regulator fitted with a means of user adjustment of the delivery pressure under normal use.

3.3 preset pressure regulator: Pressure regulator not fitted with a means of user adjustment of the delivery pressure under normal use and for which tools are required to adjust the factory preset pressure.

1) To be published. (Revision of ISO 261:1973)

3.4 single-stage pressure regulator: Pressure regulator that reduces the inlet pressure in a single stage to the required pressure.

3.5 two-stage pressure regulator: Pressure regulator that reduces the inlet pressure in two stages to the required pressure.

3.6 flowmeter: Device that measures and indicates the flow of a specific gas.

NOTE 1 It may incorporate a flow adjustment control.

3.7 flow-gauge: Gauge which measures pressure differential using ambient pressure as the datum point but which is calibrated in units of flow.

NOTE 2 The flow-gauge does not measure flow: it indicates flow by measuring the pressure upstream of a fixed orifice.

3.8 pressure gauge: Gauge which measures and indicates a pressure.

3.9 pressure regulator with flowmeter: Pressure regulator equipped with a flowmeter to measure and indicate flow.

3.10 pressure regulator with flow-gauge: Pressure regulator which incorporates a flow-gauge and orifice downstream of the flow-gauge.

3.11 pressure regulator with fixed orifice: Preset pressure regulator which incorporates one or more fixed orifices to control the flow.

3.12 high pressure [HP]: Pressure greater than 1 400 kPa (14 bar).

3.13 low pressure [LP]: Pressure of 1 400 kPa (14 bar) or less.

3.14 pressure relief valve: Preset device designed to relieve excess pressure at a preset value and protect the pressure regulator.

3.15 rated (maximum) inlet pressure, P_1: Rated (maximum) upstream pressure for which the pressure regulator is designed.

3.16 rated (maximum) outlet pressure, P_2: Rated (maximum) downstream pressure for the standard discharge Q_1, specified in the operation and maintenance manual.

3.17 test inlet pressure; upstream critical pressure, P_3: Minimum inlet pressure for the purpose of rating the flow performance (standard discharge) of the pressure regulator.

NOTE 3 It is equivalent to twice the maximum outlet pressure, P_2, plus 100 kPa, i.e. $P_3 = 2P_2 + 100$ kPa.

3.18 closure pressure, P_4: Stabilized outlet pressure 1 min after the cessation of the flow from a regulator where the flow has been set to standard discharge.

3.19 test outlet pressure, P_5: Highest or lowest value of the outlet pressure resulting from a variation in the inlet pressure between P_1 and P_3 at previously adjusted conditions, P_1, P_2, Q_1.

3.20 standard discharge, Q_1: Flow, specified in the operation and maintenance manual, for which the regulator is designed to maintain a rated outlet pressure, P_2, at test inlet pressure P_3.

3.21 pressure characteristics: Variation of outlet pressure with inlet pressure under constant flow conditions.

3.22 flow characteristics: Variation of outlet pressure in relation to the rate of flow from zero to the maximum capacity flow of the regulator with the inlet pressure remaining constant.

3.23 gas-specific: Having characteristics which prevent interchangeability and allow assignments to one gas or vacuum service only.

3.24 high-pressure regulator: Pressure regulator intended for use with inlet pressure greater than 1 400 kPa.

3.25 low-pressure regulator: Pressure regulator intended for use with inlet pressure of 1 400 kPa or less.

4 Terminology and units of measurement

4.1 Typical examples of pressure regulators and associated components are shown in figure 1.

4.2 Typical applications of pressure regulators are shown in table 1.

4.3 Unless otherwise indicated, the units of measurement are:

pressure	kPa
flow	l/min
temperature	°C

5 Materials and cleanliness

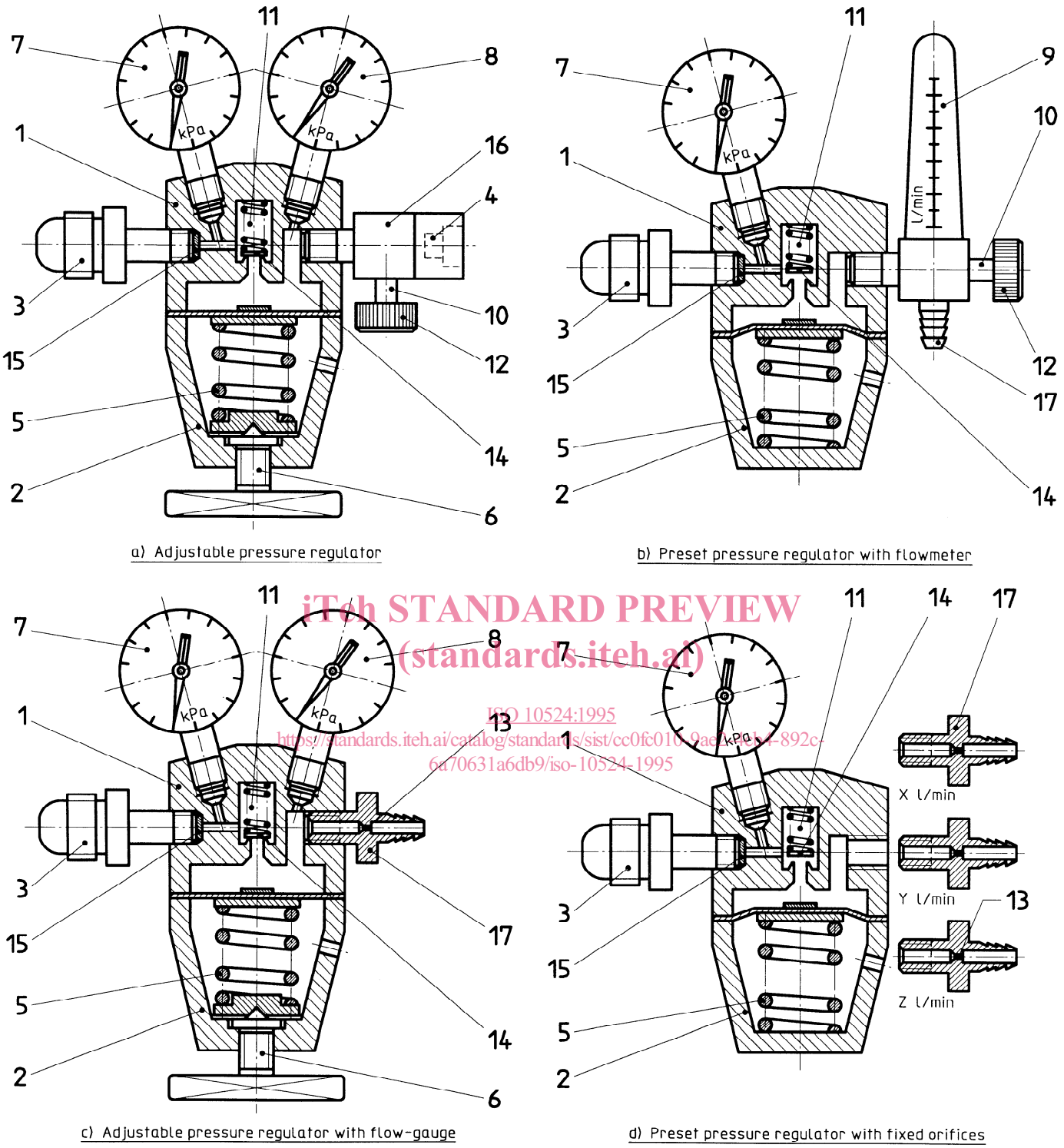
5.1 Materials

Metallic and non-metallic materials including lubricants, thread sealants and sealant rings shall be selected for the intended application and shall be compatible under operating conditions.

Extreme care should be used in the selection of materials for use with a medical gas. Materials that react normally in air may react violently in an oxygen-enriched atmosphere. Also mechanical thermal action of the gas or gases being controlled should be considered during selection of material. Springs and other moving parts liable to come in contact with the medical gas should not be plated.

5.2 Cleanliness

All surfaces in contact with the medical gas shall be cleaned for oxygen service. Any method of cleaning and degreasing may be used which effectively removes all surface dirt and hydrocarbons without leaving residues. Chemical cleaning methods will normally require a subsequent washing and drying process to remove the residues.



a) Adjustable pressure regulator

b) Preset pressure regulator with flowmeter

c) Adjustable pressure regulator with flow-gauge

d) Preset pressure regulator with fixed orifices

Key

1	Body	7	HP gauge	13	Fixed orifice
2	Cover	8	LP gauge (or flow-gauge)	14	Pressure regulator valve
3	Inlet connector	9	Flowmeter	15	Inlet filter
4	Outlet connector	10	Valve spindle	16	Outlet valve
5	Pressure regulating spring	11	Relief valve	17	Hose nipple
6	Adjusting device	12	Control knob		

Figure 1 — Typical examples of pressure regulators

Table 1 — Typical applications of pressure regulators

Type	P_1 [1] kPa	P_2 [2] kPa	Q_1 [3] l/min	Supply	Typical application
Regulators	900 to 20 000	400	60	HP gas cylinders	Single medical application [4]
Regulators	1 700 to 20 000	800	300	HP gas cylinders	Single surgical tool
Regulators with flowmeter	900 to 20 000	—	40	HP gas cylinders	Single patient use
Regulators with flow-gauge and fixed orifice	900 to 20 000	—	20	HP gas cylinders	Home care or emergency transport
Regulators	400 to 1 400	—	60	Pipeline systems	Single item of medical equipment [4]
Regulators with flowmeter	400 to 1 400	—	40	Pipeline system	Single patient use

1) Range of inlet pressure
2) Outlet pressure
3) Maximum continuous flow
4) Some medical equipment may require higher flows for a short period of time.

6 Requirements for pressure gauges and flow-gauges

ISO 5171 applies with the following amendments.

6.1 Dimensions

The connecting thread for connecting the gauges to the regulators shall comply with ISO 228-1, class B (when parallel) or ISO 7-1 (when tapered). The thread diameter shall be 1/4", 1/8", or M10 × 1 complying with ISO 261. Nominal gauge sizes other than those specified in ISO 5171 are permitted.

6.2 Scale reading

6.2.1 All markings on the scale of all pressure gauges and flow-gauges shall be legible to an operator having a visual acuity, corrected if necessary, of 1, seated or standing 1 m from the gauge at an illuminance of 215 lx.

6.2.2 For pressure gauges intended to indicate cylinder contents, the scale shall either be numbered as specified in ISO 5171 or be marked for contents as 0, 1/4, 1/2, 3/4, and full. In the latter case the maximum operating pressure of the gauge shall be marked on the dial.

NOTE 4 Pressure gauges cannot indicate the amount of liquified gas contained in a cylinder.

7 General requirements for pressure regulators, pressure regulators with flowmeters, pressure regulators with flow-gauges, pressure regulators with fixed orifices

7.1 Inlet connection

7.1.1 The inlet connection for a pressure regulator connected to a gas cylinder shall conform to ISO 407, ISO 5145 or the relevant national standard.

7.1.2 The inlet connection for a pressure regulator connected to a terminal unit shall conform to ISO 9170.

7.1.3 The torque required to remove the inlet connection from the regulator body shall be not less than 30 N·m.

7.2 Outlet connection

7.2.1 If the outlet connection is intended for user connection or disconnection, it shall be a DISS or a NIST body conforming to ISO 5359 or a quick-connector socket conforming to ISO 9170.

7.2.2 The torque required to remove the outlet connection from the regulator body shall be not less than 20 N·m.

7.3 Pressure relief valve

7.3.1 A pressure relief valve shall be provided as a component part of a pressure regulator intended for use with HP pressure cylinders to relieve excess pressure. A bursting disc shall not be used as a relief valve.

7.3.2 The pressure relief valve shall remain gas-tight to a pressure above the maximum pressure P_2, taking into account the coefficients i and R, as tested in 11.11.

The relief valve should be fitted in such a way that the gas discharge will not endanger personnel.

7.3.3 The minimum discharge, Q_{rv}, of the relief valve shall be equal to or greater than the standard discharge, Q_1, at a pressure $P_{rv} = 2P_2$, as tested in 11.11.

7.4 Filtration

7.4.1 The pressure regulator shall incorporate on the high-pressure side upstream of the regulator valve a filter with openings no greater than 100 µm or equivalent mesh.

NOTE 5 Metallic filters such as sintered bronze filters serve to retard the progress of the flame front in the event of ignition upstream of the pressure regulator.

7.5 Resistance to ignition

7.5.1 HP pressure regulators shall not ignite when submitted to oxygen pressure shocks. The test is given in 11.8.2 and 11.8.3.

7.5.2 For pressure regulators for all medical gases used on HP cylinders, each possible combination of filters and pressure regulator assemblies recommended by the manufacturer shall pass the ignition test given in 11.8.2 and 11.8.3.

7.5.3 For LP pressure regulators, the ignition temperature of the non-metallic components in contact with the gas, including the sealing materials and lubricants (if used), shall not be lower than 160 °C. The test for the determination of the ignition temperature is given in 11.8.3.

NOTE 6 This safety margin (100 °C above the maximum operating temperature) is necessary because it covers both an unforeseen increase of the operating temperature and the fact that the ignition temperature is not a constant. In this connection, it must be emphasized again that values of the ignition temperature always depend on the test method used, which does not exactly simulate all possible operating conditions.

7.6 Outlet valve

7.6.1 If a pressure regulator is fitted with an outlet valve, the torque required to remove the valve from the pressure regulator body shall be not less than 20 N·m.

7.6.2 If a pressure regulator is fitted with an outlet valve, the control knob and the valve spindle shall be captive such that they cannot be disengaged without the use of a tool.

7.7 Pressure adjusting device

7.7.1 The pressure adjusting device shall be captive and shall be removable only by the use of a tool. The pressure regulator shall be designed so that the regulator valve cannot be held in the open position as a consequence of the pressure regulator spring being compressed to its solid length.

7.7.2 It shall not be possible to set a pressure at which the relief valve lifts.

7.8 Gas tightness

Neither the external nor the internal leakage shall exceed 10 ml/h when HP and LP chambers are subjected to their respective maximum rated pressure. The test is given in 11.12.

7.9 Mechanical resistance

7.9.1 The pressure regulator shall conform to the operating characteristics given in clause 10 after the HP chamber of the pressure regulator has been pressurized to 1,5 times its rated inlet pressure, P_1, for 5 min. The test is given in 11.9.1.

7.9.2 The pressure regulator shall conform to the operating characteristics given in clause 10 after the LP chamber of the pressure regulator has been pressurized to twice its rated outlet pressure, P_2, for 5 min. The test is given in 11.9.2.

7.9.3 The HP portion of the pressure regulator shall be capable of withstanding 2,25 times its rated inlet pressure, P_1, without rupturing. The test is given in 11.9.3.

7.9.4 The LP portion of the pressure regulator shall be capable of withstanding four times its rated outlet pressure, P_2, without rupturing. The test is given in 11.9.4.

7.10 Flow characteristics

The flow characteristics shall correspond to within ±10 % of the manufacturer's published values. The test is given in 11.5.1.

7.11 Regulators for HP cylinders

Pressure regulators intended to be used with high-pressure cylinders shall be fitted with a high-pressure gauge.

7.12 Pressure gauges and flow-gauges

7.12.1 Pressure gauges and flow-gauges shall meet the requirements given in clause 6.

7.12.2 The torque required to remove the pressure gauge(s) and the flow-gauge from the pressure regulator body or from the outlet valve body shall be not less than 20 N·m.

8 Environmental temperatures

8.1 Storage temperature

The pressure regulator shall be capable of being stored at temperatures of − 40 °C and + 70 °C for 4 h each. After exposure to these temperatures, the pressure regulator shall comply with the requirements of this International Standard.

NOTE 7 There is no requirement to test the pressure regulator function at the storage temperatures.

8.2 Operating temperature

8.2.1 Following exposure to the storage temperatures as specified in 8.1, the pressure regulator shall function in accordance with the requirements of this International Standard and the manufacturer's specifications at operating temperatures of − 20 °C and + 60 °C.

8.2.2 The temperature requirement does not apply to 9.1.2, 9.2.2, 9.3.4, 10.1 and 10.2.

9 Special requirements

9.1 Requirements for pressure regulators with flowmeter

9.1.1 Flow control valve

If a pressure regulator with flowmeter is fitted with a flow control valve, the control knob and the valve spindle shall be captive such that they cannot be disengaged without the use of a tool.

The flow control valve shall be designed so that the flow increases when the knob is turned counter-clockwise.

9.1.2 Accuracy of flowmeter

The accuracy of the flow at any flow graduation of a flowmeter shall be within + 10 % of the indicated value for flows between 10 % and 100 % of full scale or ± 0,5 l/min, whichever is the greater.

For a flowmeter with a full scale of less or equal to 1 l/min, the accuracy of the flow at any flow graduation shall be within ± 10 % of the indicated value.

The accuracy shall be measured at P_2 when the flow is discharged into an ambient atmosphere of 101,3 kPa at an operating temperature of 23 °C. The test is given in 11.13.

9.1.3 Scale and indicators of flowmeter

The flowmeter shall be graduated in units of litres or millilitres per minute.

The scale of the flowmeter shall be legible to an operator having visual acuity of 1, corrected if necessary, seated or standing 1 m from the flowmeter at an illuminance of 215 lx.

9.1.4 Pressure of flowmeter

The flowmeter shall be capable of containing or safely relieving a pressure of $2P_2$. The test is given in 11.10. Following this test the flowmeter shall meet the requirements given in 9.1.2.

9.1.5 Removal of flowmeter

The torque required to remove the flowmeter from the pressure regulator body shall not be less than 20 N·m.