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Date: 10 March 2025

Origin: International

Latest date for receipt of comments: 03 May 2025

Project No. 2023/01298

Responsible committee: CH/121/6 Medical gas supply systems

Interested committees:

Title: Draft BS EN ISO 10524-3 Pressure regulators for use with medical gases. Part 3: Pressure regulators integrated with cylinder valves (VIPRs).

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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

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Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 10524-3

Pressure regulators for use with medical gases —

Part 3: Pressure regulators integrated with cylinder valves (VIPRs)

Détendeurs pour l'utilisation avec les gaz médicaux —

Partie 3: Détendeurs intégrés dans les robinets des bouteilles à gaz (VIPR)

ICS: 11.040.10

ISO/TC 121/SC 6

Secretariat: **ANSI**

Voting begins on:
2025-03-10

Voting terminates on:
2025-06-02

This document is circulated as received from the committee secretariat.

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Reference number
ISO/DIS 10524-3:2025(en)

Full document details: 25/30475288 DC

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Published in Switzerland

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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.

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 of 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 www.iso.org/iso/foreword.html.

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 10524-3:2019), which has been technically revised.

The main changes are as follows:

- reorganisation of the structure of the document
- Alignment on the requirements of ISO 10297:2024, Gas cylinders — Cylinder valves — Specification and type testing
- Alignment of terms with ISO 10297 and ISO 15002
- New requirement regarding the potential contamination of the gas pathway
- New requirement regarding cleaning and disinfection
- Definition of three temperature ranges
- References to colour coding have been removed
- Specific requirements for *VIPRs* intended to supply air or nitrogen for driving surgical tools moved to an normative annex
- New informative annex on qualification of a *VIPR* for use in an air / road ambulance
- New informative annex on the promoted ignition test (ASTM G175-24)

A list of all parts in the ISO 10524 series can be found on the ISO website.

214 Any feedback or questions on this document should be directed to the user's national standards
215 body. A complete listing of these bodies can be found at www.iso.org/members.html.
216

217 Introduction

218 Medicinal gases can be supplied in cylinder fitted with *Valves with Integrated Pressure*
 219 *regulators (VIPRs)*. High pressure cylinders fitted with a *VIPR* offers the patient and the
 220 healthcare professional with a safe and convenient package to administer the gas without
 221 having to connect a separate *pressure regulator*.

222 The *VIPR* is normally fitted with an *integral flow control device* incorporating a *flow outlet* to
 223 allow the prescribed flow to be administered and can be fitted with a *pressure outlet*, using a
 224 *gas-specific* terminal outlet, as used for medical gas pipeline systems.

225 In order for the medicinal gas to be administered safely to the patient, the design
 226 specifications and characteristics of the *VIPR* need to be controlled to ensure that the flows
 227 and pressures are compatible with any medical devices used with the cylinder package.

228 This standard describes basic requirements for the *VIPRs* used with medical gas cylinder
 229 packages including:

- 230 • Suitable materials of construction, compatible with the medicinal gases
- 231 • Safe design principles, including requirements for:
 - 232 • usability and handling;
 - 233 • mechanical strength,
 - 234 • operational characteristics (flowrates and pressures);
 - 235 • pressure relief systems;
 - 236 • product integrity (leakage);
 - 237 • resistance to ignitions.
- 238 • Gas-specificity
- 239 • Cleanliness
- 240 • Marking
- 241 • Information for safe usage by the medical gas supplier and the end user

242 The standard describes the approved tests for the type testing of the *VIPR* and the acceptance
 243 limits for the tests.

244 *VIPRs* also act as the “closure” of gas cylinders, and both gas cylinders and closures are subjected
 245 to transport regulations. ISO 10297, *Gas cylinders — Cylinder valves — Specification and type*
 246 *testing* standard, developed by ISO/TC 58/SC 2 is the ISO cylinder valve (closure) standard
 247 referenced in these regulations. ISO 10297 includes industrial and medical *VIPRs* within its scope
 248 and was recently revised,

249 Medical *VIPRs* are classified as medical devices and have to comply with the medical device
 250 regulations. As a medical device standard, ISO 10524-3 is intended to demonstrate conformity
 251 with the safety and performance requirements as defined in medical devices regulations and
 252 recognised guidelines. As, ISO 10524-3 strives to comprehensively cover all aspects related to
 253 safety and performances of the medical *VIPR*, it makes having a general reference to ISO 10297
 254 impractical.

255 In order to reconcile these regulatory constraints and minimize burden on manufacturers, the
 256 chosen approach is to replicate the applicable “medical” requirements common to both standards
 257 within ISO 10524-3, along with a note indicating alignment with ISO 10297:2024. Some of the
 258 requirements of ISO 10297 are not relevant for medical devices and have not been duplicated.

259 However, for those tests methods that are relevant, direct reference to ISO 10297:2024 is made,
 260 so avoiding duplication.

1 Scope

This document specifies design, type testing, and marking requirements for cylinder valves with integrated *pressure regulators* [as defined in 3.26 and referred to hereafter as *valves with integrated pressure regulators (VIPRs)*].

Medical *VIPRs* are designed to be mounted on medical gas cylinders, allowing them to be filled with medical gases for subsequent use as a supply source for other medical devices, such as emergency ventilators, or for the direct administration of medical gases to a patient via an *integral flow control device*, when fitted.

Examples of medical gases include oxygen, medical air and oxygen/nitrous oxide mixtures.

Intended use of *VIPRs* may also encompass the supply of air or nitrogen for driving surgical tools.

NOTE See annex B for their specific requirements

This document applies to *VIPRs* mounted on refillable cylinders with a *working pressure* up to 30 000 kPa (300 bar) intended to be filled in cylinder filling facilities or on self-filling systems as used in homecare applications.

VIPRs covered by this document are pressure pre-set and provided with a *pressure outlet* and/or pre-set *flow outlet(s)*.

VIPRs used for self-fill systems used in homecare are not covered by this standard, but it can be used as a guide.

NOTE The conditions of use for these *VIPRs* vary significantly, particularly in terms of filling frequency and usage, which can occur daily throughout their lifetime.

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 5145, *Gas cylinders — Cylinder valve outlets for gases and gas mixtures — Selection and dimensioning*

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

ISO 10297:2024, *Gas cylinders — Cylinder valves — Specification and type testing*

ISO 11114-6, *Gas cylinders — Compatibility of cylinder and valve materials with gas contents — Part 6: Oxygen pressure surge testing*

ISO 11117, *Gas cylinders — Valve protection caps and valve guards — Design, construction and tests*

ISO 11363-1, *Gas cylinders — 17E and 25E taper threads for connection of valves to gas cylinders — Part 1: Specifications*

ISO 13341, *Gas cylinders — Fitting of valves to gas cylinders*

- 298 ISO 14971, *Medical devices — Application of risk management to medical devices*
 299 ISO 15001, *Anaesthetic and respiratory equipment — Compatibility with oxygen*
 300 ISO 15245-1, *Gas cylinders — Parallel threads for connection of valves to gas cylinders — Part 1:*
 301 *Specification*
 302 ISO 15996, *Gas cylinders — Residual pressure valves — Specification and type testing of cylinder*
 303 *valves incorporating residual pressure devices*
 304 ISO 17256, *Anaesthetic and respiratory equipment — Respiratory therapy tubing and connectors*
 305 ISO 20417, *Medical devices — Information to be supplied by the manufacturer*
 306 EN 837-1, *Pressure gauges — Part 1: Bourdon tube pressure gauges — Dimensions, metrology,*
 307 *requirements and testing*

308 **3 Terms and definitions**

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

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

- 312 — ISO Online browsing platform: available at <https://www.iso.org/obp>
- 313 — IEC Electropedia: available at <http://www.electropedia.org/>

314 **3.1**

315 **accuracy of flow**

316 difference between the indicated flow and the measured flow

317 Note 1 to entry: Expressed as a percentage.

318 **3.2**

319 **content indicator**

320 device that indicates the cylinder content

321 Note 1 to entry: The content can be expressed either in percentage of content, volume of gas or cylinder
 322 pressure.

323 **3.3**

324 **filling adaptor**

325 means of connecting the *VIPR filling port* to the filling system allowing a cylinder fitted with a
 326 *VIPR* to be filled or vented

327 Note 1 to entry: This is not part of the *VIPR*.

328 Note 2 to entry: It may also be referred to as a filling tool.

329 **3.4**

330 **filling port**

331 connector on the *VIPR* through which the cylinder is filled

332 **3.5**

333 **filling port non-return valve**

334 valve which remains closed in normal use thus preventing the flow out of the *VIPR's filling port*
 335 until opened by insertion of an appropriate means and which then permits flow in either
 336 direction

337 Note 1 to entry: Some *filling port non-return valves* may also be opened by the pressure of the incoming gas.

338 3.6

339 flow outlet

340 outlet intended to deliver a controlled flow of gas

341 3.7

342 flow selector

343 means for selecting the flow and indicating the flow selected

344 3.8

345 guard

346 A protective device for the *VIPR*, optionally providing features for handling, bed hanging,
347 aesthetics, and easy cleaning.

348 It can be fixed to the *VIPR* only or to the cylinder neck.

349 3.9

350 gas-specific

351 having characteristics that prevent connection between different gas services

352 3.10

353 integral flow control device

354 device integrated in the *VIPR* that enables the delivery of a preset controlled flow of gas via a *flow*
355 *outlet*. A *flow selector* enables the user to choose the desired flow rate from the available settings.

356 3.11

357 nipple

358 portion of a connector which is pushed into and secured within the bore (lumen) of a hose

359 3.12

360 nominal inlet pressure

361 P_1

362 *working pressure* of the cylinder specified by the manufacturer of the *VIPR* for which the *VIPR* is
363 intended to be used

364 3.14

365 outlet pressure

366 P_2

367 pressure supplied by the *VIPR* at the *pressure outlet*

368 3.15

369 oxidizing gas

370 gas or gas mixture more oxidizing than air

371 EXAMPLE:

372 Any gas or gas mixture that is able, at atmospheric pressure, to support the combustion greater than or
373 equal to a reference oxidizer consisting of 23,5 % oxygen in nitrogen.

374 Note 1 to entry: Derived from ISO 10156^[10].

375 3.16

376 pre-set pressure regulator

377 *pressure regulator* that is not provided with a means of operator adjustment of the *outlet pressure*

378 **3.17**

379 **pressure outlet**

380 outlet intended to deliver gas at a controlled pressure

381 **3.18**

382 **pressure regulator**

383 device that reduces the inlet pressure and maintains the set *outlet pressure* within specified limits

384 Note to entry: in ISO 10297, a “*pressure regulator*” is called a “pressure regulating system”

385 **3.19**

386 **pressure-relief device**

387 device intended to relieve excess pressure at a pre-set value

388 **3.20**

389 **primary valve operating mechanism**

390 primary mechanism which closes and opens the valve orifice and which includes the internal and
391 external sealing systems

392 Note 1 to entry: In the previous version of this standard, the *primary valve operating mechanism* was called
393 the main shut-off.

394 Note 2 to entry: For *VIPR type B* designs, the valve of the *pressure regulator* acts as the *primary valve*
395 *operating mechanism*.

396 Note 3 to entry: For *VIPR type C* designs, a low pressure shut-off valve or, if not fitted, the *pressure outlet*
397 check valve and/or the flow selection mechanism acts as the *primary valve operating mechanism*.

398 Note 4 to entry: in ISO 10297, the *primary valve operating mechanism* is called the valve operating
399 mechanism

400 **3.21**

401 **residual pressure device**

402 **RPD**

403 device that is designed to prevent ingress of contaminants by maintaining a positive pressure
404 within the cylinder relative to atmosphere by closing off its internal gas passages in the
405 discharging direction

406 [SOURCE:ISO 15996:2017, 3.2]

407 **3.22**

408 **expected service life**

409 time period specified by the manufacturer during which the medical device or accessory is
410 expected to remain safe and effective for use

411 [SOURCE: ISO 20417:2020, 3.7]

412 **3.23**

413 **single fault condition**

414 condition in which a single means for protection against a safety hazard in equipment is defective
415 or a single external abnormal condition is present

416 **3.25**

417 **valve inlet connection**

418 threaded connection of the *VIPR* which connects it to the cylinder

419 Note 1 to entry: It can also be referred to as the valve stem.

3.26

valve with integrated pressure regulator

VIPR

combination of a *pressure regulator* and cylinder valve intended to be fitted to a medical gas cylinder

3.27

VIPR type A

VIPR design where the *primary valve operating mechanism* is located upstream of the *pressure regulator*

Note 1 to entry: For typical designs, see Annex A Fig.A1.

[SOURCE:ISO 10297:2024, 3.6]

3.28

VIPR type B

VIPR design where the *pressure regulator* is also acting as the *primary valve operating mechanism*

Note 1 to entry: For typical designs, see Annex A Fig.A2.

[SOURCE:ISO 10297:2024, 3.7]

3.29

VIPR type C

VIPR design where the *primary valve operating mechanism* is located downstream of the *pressure regulator*

Note 1 to entry: The *primary valve operating mechanism* can be a *flow selector*.

Note 2 to entry: For typical designs, see Annex A Fig.A3.

[SOURCE: ISO 10297:2024, 3.8]

3.30

working pressure

settled pressure of a compressed gas at a uniform reference temperature of 15 °C in a full gas cylinder

Note 1 to entry: This definition does not apply to liquefied gases (e.g. carbon dioxide) (adapted from ISO 10297).

4 Nomenclature

The terminology used in this document for components of *VIPRs* is given in a labelled diagram in **Annex A**.

5 General requirements

5.1 Safety

a) *VIPRs*, once fitted to a gas cylinder, and maintained according to the manufacturer's instructions, shall not present any unacceptable risk, as identified, estimated and evaluated using risk management procedures in accordance with ISO 14971, under normal condition or *single fault condition*, when transported, stored, and operated in normal use.

NOTE A situation in which a fault is not detected is considered a normal condition. Fault conditions/hazardous situations can remain undetected over a period of time and as a consequence can lead to an unacceptable risk. In that case, a fault condition subsequently detected is considered as a *single fault condition*. Specific risk control measures to deal with such situations is determined within the risk management process.

b) The risks associated with the ignition of metallic and non-metallic materials in an oxygen-enriched environment, including the potential release of toxic products, shall be assessed according to the principles defined in ISO 15001.

c) The design of the *VIPR* should be such that in the event of internal ignition, the consequences of the ignition are contained and the gas vented safely by the *VIPR*.

Check conformance by inspection of the risk management file.

5.2 Usability

The manufacturer shall address, in a usability engineering process, any risks resulting from poor usability.

NOTE For information related to usability, see other standards, for example IEC 62366-1 and IEC/TR 62366-2.

The following tasks should be considered:

- by the gas supplier
 - carrying and handling the cylinder
 - filling the cylinder
- by the health personal or the patient
 - carrying the cylinder
 - opening the cylinder (*VIPR type A*)
 - checking the status of the cylinder (open or closed)
 - checking the content of the cylinder
 - connecting a device/flexible hose to the *pressure outlet*
 - connecting a therapy tube to the *nipple*
 - identifying in which direction turn the *flow selector*
 - selecting a flow rate
 - reading the flow rate (legibility)
 - reading the content indicator (legibility)
- by the maintenance operators
 - maintenance operations as defined in the instruction for use

Check conformance by inspection of the usability engineering file.

5.3 Materials

a) The materials which come in contact with the medical gas in normal condition shall be compatible with the intended medical gas and oxygen, in the temperature range specified in 6.1.

NOTE 1 Oxygen compatibility is usually defined as the ability of a material to coexist with oxygen and a potential source(s) of ignition. The aim of using oxygen-compatible materials is to develop a system design which has a low probability of ignition and minor consequences based on the use of materials exhibiting good compatibility and low energy release if ignited or by minimizing the quantities of non-metallic components.