DIN EN ISO 7396-1

ICS 11.040.10

Supersedes
DIN EN ISO 7396-1:2016-09

Medical gas pipeline systems – Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1:2016 + Amd 1:2017); English version EN ISO 7396-1:2016 + A1:2019, English translation of DIN EN ISO 7396-1:2019-06

Rohrleitungssysteme für medizinische Gase –
Teil 1: Rohrleitungssysteme für medizinische Druckgase und Vakuum (ISO 7396-1:2016 + Amd 1:2017);
Englische Fassung EN ISO 7396-1:2016 + A1:2019,
Englische Übersetzung von DIN EN ISO 7396-1:2019-06

Systèmes de distribution de gaz médicaux –
Partie 1: Systèmes de distribution de gaz médicaux comprimés et de vide (ISO 7396-1:2016 + Amd 1:2017);
Version anglaise EN ISO 7396-1:2016 + A1:2019,
Traduction anglaise de DIN EN ISO 7396-1:2019-06

Document comprises 196 pages

Translation by DIN-Sprachendienst.

In case of doubt, the German-language original shall be considered authoritative.

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A comma is used as the decimal marker.

National foreword

This document (EN ISO 7396-1:2016 + A1:2019) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment" (Secretariat: BSI, United Kingdom).

The responsible German body involved in its preparation was *DIN-Normenausschuss Rettungsdienst und Krankenhaus* (DIN Standards Committee Rescue Services and Hospital), Working Committee NA 053-03-06 AA "Central gas supply systems".

This standard includes Amendment 1 approved by CEN on 2018-12-13.

The start and finish of text introduced or altered by amendment is indicated in the text by tags ▌A1⟩ ⟨A1▌.

Subclause 5.5.2.1 of this document specifies a maximum value of 5 ml/m^3 (5 ppm (*V/V*)) for the carbon monoxide concentration in medical air. This value has been taken from the European Pharmacopoeia for "medicinal air".

Carbon monoxide, CO, is a colourless, odourless, tasteless and toxic gas. The gas is toxic as it forms a stronger bond with haemoglobin than oxygen does, thus preventing the transport of oxygen in the blood.

This document therefore specifies the provision of an operating alarm in the event of a threshold value being exceeded. According to subclause 6.4 g), the alert threshold for the carbon monoxide concentration based on the USP Medicinal Air monograph is 10 ml/m^3 (10 ppm (*V/V*)). In this subclause, attention is drawn to the fact that a lower value may be specified due to regional or local regulations. For Germany, the requirements of the European Pharmacopoeia apply. As a result, in Germany, an operating alarm shall be triggered if the CO level exceeds 5 ml/m^3 (5 ppm (*V/V*)). Medical air from a compressor system or oxygen 93 from a concentrator system shall then be supplied.

Subclause 5.8 specifies requirements for the location of supply systems. For occupational exposure limit values, the TRGS 900 *"Arbeitsplatzgrenzwerte"* is to be considered in Germany (see www.baua.de).

The DIN documents corresponding to the international documents referred to in this document are as follows:

ISO 407:2004	DIN EN ISO 407:2005-02
ISO 3746:2010	DIN EN ISO 3746:2011-03
ISO 4126-1	DIN EN ISO 4126-1
ISO 4135	DIN EN ISO 4135
ISO 5359:2014	DIN EN ISO 5359:2018-05
ISO 7396-2	DIN EN ISO 7396-2
ISO 9001:2015	DIN EN ISO 9001:2015-11
ISO 9170-1:2008	DIN EN ISO 9170-1:2008-10
ISO 10524-2:2005	DIN EN ISO 10524-2:2006-07
ISO 10524-4	DIN EN ISO 10524-4
ISO 11114-1	DIN EN ISO 11114-1
ISO 11114-2	DIN EN ISO 11114-2
ISO 11197:2004	DIN EN ISO 11197 (VDE 0750-211):2016-08
ISO 13485:2003	DIN EN ISO 13485:2010-01
ISO 13585:2012	DIN EN ISO 13585:2012-10
ISO 14644-1:1999	DIN EN ISO 14644-1:2016-06

ISO 14971:2007	DIN EN ISO 14971:2013-04
ISO 15001:2010	DIN EN ISO 15001:2012-06
ISO 17672:2010	DIN EN ISO 17672:2017-01
ISO 18082:2014	DIN EN ISO 18082:2017-12
ISO 21969:2009	DIN EN ISO 21969:2010-04
IEC 60601-1-8:2006	DIN EN 60601-1-8 (VDE 0750-1-8):2014-04
ISO 80601-2-69:2014	DIN EN ISO 80601-2-69:2014-12

Amendments

This standard differs from DIN EN ISO 7396-1:2016-09 as follows:

a) subclause 5.8 “Location of supply systems” has been updated.

Previous editions

DIN 13260-1: 1990-12
DIN EN 737: 1998-11, 2000-01
DIN ISO 10083: 2008-12
DIN EN ISO 7396-1: 2007-07, 2010-08, 2016-09
DIN EN ISO 7396-1/A3: 2013-07

National Annex NA
(informative)

Bibliography

DIN EN 60601-1-8:2014-04 (VDE 0750-1-8), *Medical electrical equipment — Part 1-8: General requirements for basic safety and essential performance — Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2006 + A1:2012)*

DIN EN ISO 407:2005-02, *Small medical gas cylinders — Pin-index yoke-type valve connections (ISO 407:2004)*

DIN EN ISO 3746:2011-03, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane (ISO 3746:2010)*

DIN EN ISO 4126-1, *Safety devices for protection against excessive pressure — Part 1: Safety valves*

DIN EN ISO 4135, *Anaesthetic and respiratory equipment — Vocabulary*

DIN EN ISO 5359:2018-05, *Anaesthetic and respiratory equipment — Low-pressure hose assemblies for use with medical gases (ISO 5359:2014 + Amd 1:2017)*

DIN EN ISO 7396-2, *Medical gas pipeline systems — Part 2: Anaesthetic gas scavenging disposal systems*

DIN EN ISO 9001:2015-11, *Quality management systems — Requirements (ISO 9001:2015)*

DIN EN ISO 9170-1:2008-10, *Terminal units for medical gas pipeline systems — Part 1: Terminal units for use with compressed medical gases and vacuum (ISO 9170-1:2008)*

DIN EN ISO 10524-2:2006-07, *Pressure regulators for use with medical gases — Part 2: Manifold and line pressure regulators (ISO 10524-2:2005)*

DIN EN ISO 10524-4, *Pressure regulators for use with medical gases — Part 4: Low-pressure regulators*

DIN EN ISO 11114-1, *Gas cylinders — Compatibility of cylinder and valve materials with gas contents — Part 1: Metallic materials*

DIN EN ISO 11114-2, *Gas cylinders — Compatibility of cylinder and valve materials with gas contents — Part 2: Non-metallic materials*

DIN EN ISO 11197 (VDE 0750-211):2016-08, *Medical supply units (ISO 11197:2016)*

DIN EN ISO 13485:2010-01, *Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2003 + Cor. 1:2009)*

DIN EN ISO 13585:2012-10, *Brazing — Qualification test of brazers and brazing operators (ISO 13585:2012)*

DIN EN ISO 14644-1:2016-06, *Cleanrooms and associated controlled environments — Part 1: Classification of air cleanliness by particle concentration (ISO 14644-1:2015)*

DIN EN ISO 14971:2013-04, *Medical devices — Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)*

DIN EN ISO 15001:2012-06, *Anaesthetic and respiratory equipment — Compatibility with oxygen (ISO 15001:2010)*

DIN EN ISO 17672:2017-01, *Brazing — Filler metals (ISO 17672:2016)*

DIN EN ISO 18082:2017-12, *Anaesthetic and respiratory equipment — Dimensions of non-interchangeable screw-threaded (NIST) low-pressure connectors for medical gases (ISO 18082:2014 + Amd. 1:2017)*

DIN EN ISO 21969:2010-04, *High-pressure flexible connections for use with medical gas systems (ISO 21969:2009)*

DIN EN ISO 80601-2-69:2014-12, *Medical electrical equipment — Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment (ISO 80601-2-69:2014)*

DIN ISO 7183, *Compressed air dryers — Specifications and testing*

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EUROPEAN STANDARD

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English Version

Medical gas pipeline systems — Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1:2016 + Amd 1:2019)

Systèmes de distribution de gaz médicaux — Partie 1: Systèmes de distribution de gaz médicaux comprimés et de vide (ISO 7396-1:2016 + Amd 1:2019)

Rohrleitungssysteme für medizinische Gase — Teil 1: Rohrleitungssysteme für medizinische Druckgase und Vakuum (ISO 7396-1:2016 + Amd 1:2019)

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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Contents

European foreword

This document (EN ISO 7396-1:2016) has been prepared by Technical Committee ISO/TC 121 "Anaesthetic and respiratory equipment" in collaboration with Technical Committee CEN/TC 215 "Respiratory and anaesthetic equipment", the secretariat of which is held by BSI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2016, and conflicting national standards shall be withdrawn at the latest by March 2019.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

This document supersedes EN ISO 7396-1:2007.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this document.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 7396-1:2016 has been approved by CEN as EN ISO 7396-1:2016 without any modification.