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BSI Standards Publication

Terminal units for medical gas pipeline systems

Part 1: Terminal units for use with compressed medical gases and vacuum

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National foreword

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The UK participation in its preparation was entrusted to Technical Committee CH/121/6, Medical gas supply systems.

A list of organizations represented on this committee can be obtained on request to its secretary.

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European foreword

This document (EN ISO 9170-1:2020) 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of an identical text or by endorsement, at the latest by December 2020, and conflicting national standards shall be withdrawn at the latest by June 2023.

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

This document supersedes EN ISO 9170-1:2008.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association.

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Endorsement notice

The text of ISO 9170-1:2017 has been approved by CEN as EN ISO 9170-1:2020 without any modification.

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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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Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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 ISO/TC 121, *Anaesthetic and respiratory equipment*, Subcommittee SC6, *Medical gas systems*.

This third edition cancels and replaces the second edition (ISO 9170-1:2008), which has been technically revised.

This edition includes the following significant changes with respect to the previous edition:

a) oxygen 93, detailing marking and colour coding, was introduced;

b) figures for test conditions were clarified.

A list of all parts in the ISO 9170 series can be found on the ISO website.

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Introduction

Terminal units are the points on a medical gas pipeline system where the operator makes connections and disconnections for the supply of specified medical gases to anaesthetic machines, lung ventilators or other items of medical equipment. Terminal units are also used for vacuum pipeline systems. A wrong connection can create a hazard to the patient or operator. It is important that terminal units and their components be designed, manufactured, installed and maintained in such a way as to meet the requirements specified in this document.

This document pays particular attention to

— suitability of materials,

— gas-specificity,

— cleanliness,

— testing,

— identification, and

— information supplied.

This document contains information for the installation and testing of terminal units prior to use. Testing of terminal units prior to use is critical to patient safety, and it is essential that terminal units are not used until full testing in accordance with ISO 7396-1 has been completed.

Annex A contains rationale statements for some of the requirements of this document. The clauses and subclauses marked with an asterisk (*) after their number have corresponding rationale contained in Annex A, included to provide 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 also expedite any subsequent revisions.

Annex B contains environmental aspects that should be considered.

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Terminal units for medical gas pipeline systems —

Part 1: Terminal units for use with compressed medical gases and vacuum

1 Scope

This document is intended especially to ensure the gas-specific assembly, mechanical resistance, flow, leakage and pressure drop of terminal units and to prevent their interchange between different gases and services and applies to terminal units:

a) intended for use in medical gas pipeline systems in accordance with ISO 7396-1;

b) used as pressure outlets on pressure regulators in accordance with ISO 10524-1;

c) used as pressure outlets on pressure regulators integrated with cylinder valves (VIPR) in accordance with ISO 10524-3.

This document applies to terminal units for use with the following gases for administration to patients or for medical uses (A):

— oxygen (A);

— nitrous oxide (A);

— medical air (A);

— carbon dioxide (A);

— oxygen/nitrous oxide mixture (A);

— helium/oxygen mixtures (A);

— oxygen 93 (A);

— gases and gas mixtures classified as medical device (A);

— gases delivered to medical devices or intended for medical purposes (A);

— gases and gas mixtures for medicinal use not specified above (A).

This document applies to terminal units for use with the following gases (B):

— air for driving surgical tools (B);

— nitrogen for driving surgical tools (B).

This document applies to terminal units for use with vacuum systems (C).

NOTE The requirements of this document can be used as guidelines for terminal units for other gases. These other gases will be considered for inclusion in this document when they come into general use.

This document specifies requirements for terminal units for supply and disposal of nitrogen and air for driving surgical tools.

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This document specifies requirements for probes intended to be connected to the gas-specific connection point.

This document does not specify the dimensions of probes or of the gas-specific connection points.

NOTE Regional or national standards specifying dimensions of probes and gas-specific connection points are given in the Bibliography.

Other connection systems in national use may be acceptable under this document. Dimensioning for such connections will be specified by their respective national standards.

This document does not specify the requirements for terminal units for anaesthetic gas scavenging systems (AGSS), which are specified in ISO 9170-2.

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 5359:2014, *Low-pressure hose assemblies for use with medical gases*

ISO 6506-1, *Metallic materials — Brinell hardness test — Part 1: Test method*

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

ISO 11114-3, *Transportable gas cylinders — Compatibility of cylinder and valve materials with gas contents — Part 3: Autogenous ignition test in oxygen atmosphere*

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15001:2010, *Anaesthetic and respiratory equipment — Compatibility with oxygen*

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/

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

NOTE A diagram of a typical terminal unit and probe, with an example of terminology, is shown in Figure 1.

3.1
diameter-index safety system connector
DISS connector
any of a range of male and female components intended to maintain gas specificity by allocation of a set of different diameters to the mating connectors for each particular gas

3.2
gas specific
having characteristics which prevent connections between different gas services or vacuum services

3.3
gas-specific connection point
part of the socket which is the receptor for a gas-specific probe

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3.4
gas-specific connector
connector with dimensional characteristics that prevent connections between different gas services

Note 1 to entry: Examples of gas-specific connectors are *quick connectors* (3.14), screw-threaded connectors, *diameter-index safety system (DISS) connectors* (3.1), *non-interchangeable screw-threaded (NIST) connectors* (3.11) or *sleeve indexed (SIS) connectors* (3.16).

3.5
low-pressure hose assembly
assembly consisting of a flexible hose with permanently attached gas-specific inlet and outlet connectors and designed to conduct a *medical gas* (3.7) at pressures less than 1 400 kPa and vacuum

3.6
medical device gas
any gas or mixture of gases intended by the manufacturer to be used for human beings for the purpose of

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— investigation, replacement or modification of the anatomy or of a physiological process,

— control of conception,

and does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

Note 1 to entry: In Europe, these gases are classified as a medical device in accordance with Directive 93/42/EC.

3.7
medical gas
any gas or mixture of gases having properties for treating or preventing disease in human beings which may be used in or administered either with a view to restore, correct or modify physiological functions by exerting a pharmacological, immunological or metabolic action, or to make a medical diagnosis

Note 1 to entry: This is also sometimes referred to as medicinal gas.

Note 2 to entry: In Europe, this is classified as a medicinal product in accordance with Directive 2001/83/EC.

3.8
medical gas pipeline system
complete system which comprises a supply system, a monitoring and alarm system and a distribution system with terminal units at the points where *medical gases* (3.7) or vacuum may be required

3.9
medical gas supply system
either

a) a medical gas pipeline system, or

b) an installation having no permanent pipeline system but employing a *medical gas* (3.7) supply source complete with pressure regulator(s)

3.10
nominal distribution pressure
pressure which the *medical gas pipeline system* (3.8) is intended to deliver at the terminal units

Note 1 to entry: Unless otherwise specified, pressures in this document are expressed as gauge pressures (i.e. atmospheric pressure is defined as 0 kPa gauge pressure).

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