BS EN ISO 9170-1:2020

BSI Standards Publication

Terminal units for medical gas pipeline systems

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

bsi.

National foreword

This British Standard is the UK implementation of EN ISO 9170-1:2020. It is identical to ISO 9170-1:2017. It supersedes BS EN ISO 9170-1:2008, which is withdrawn.

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.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

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Prises murales pour systèmes de distribution de gaz médicaux - Partie 1: Prises murales pour les gaz médicaux comprimés et le vide (ISO 9170-1:2017)

Entnahmestellen für Rohrleitungssysteme für medizinische Gase - Teil 1: Entnahmestellen für medizinische Druckgase und Vakuum (ISO 9170-1:2017)

This European Standard was approved by CEN on 15 April 2020.

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EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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of an identical text or by endorsement, at the latest by December 2020, and conflicting national standards shall be withdrawn at the latest by June 2023.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.

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, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

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

Contents

Page

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.

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.

INTERNATIONAL STANDARD **ISO 9170-1:2017(E)**

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.